FEDERAL REGISTER

VOLUME 12 NUMBER 67

Washington, Friday, April 4, 1947

TITLE 6—AGRICULTURAL CREDIT

Chapter I—Farm Credit Administration, Department of Agriculture

PART 10—FEDERAL LAND BANKS

PART 11—NATIONAL FARM LOAN ASSOCIATIONS

PARTIAL RETIREMENT OF STOCK

Chapter I, Title 6, Code of Federal Regulations, is hereby amended by revoking §§ 11.172 (11 F. R. 1693) and 11.258–50 (CFR, 1945 Supp.; 10 F. R. 9518) and adding § 10.279–50 to read as follows:

§ 10.279–50 *Partial retirement of stock.* In individual cases where the amount of bank stock held as security for a loan is substantially in excess of 5 percent of the unpaid balance of the loan and the bank determines that retirement of the excess stock is advisable, the Administration approves, under section 7 of the Federal Farm Loan Act (12 U. S. C. 721), the retirement of that portion of such stock which is in excess of 5 percent of the unpaid balance of the loan, *Provided,* (a) The capital stock of the association through which the existing loan was made is not impaired and such stock retirement will not make the principal remaining unpaid upon mortgages already received from the association exceed 20 times the amount of stock in the bank owned by such association, or the only stock outstanding in connection with the existing loan is bank stock, and (b) Such retirement of stock is in accordance with authorization given by the bank's board of directors by appropriate resolution. (Sec. 7, 39 Stat. 365, sec. 6, 47 Stat. 14, 12 U. S. C. 665, 721)

[SEAL] CARL COLVIN,
Acting Land Bank Commissioner.

[F. R. Doc. 47-3242; Filed, Apr. 3, 1947; 8:46 a. m.]

TITLE 7—AGRICULTURE

Subtitle A—Office of Secretary of Agriculture

PART 7—PRICE DECONTROL AND RECONTROL

CERTIFICATION OF AGRICULTURAL COMMODITIES IN SHORT SUPPLY

Pursuant to the authority vested in me by the Emergency Price Control Act of 1942, as amended, and particularly by section 1A (e) of said act as added by the Price Control Extension Act of 1946, I hereby determine and certify to the Temporary Controls Administrator that no modifications in the certification of commodities in short supply (§ 7.50 *Certification of Agricultural commodities in short supply*), made on September 1, 1946, as amended (11 F. R. 9669, 11349, 13135, 14063; 12 F. R. 60, 825, 1475), should be and none are hereby made.

(Pub. Law 548, 79th Cong., 2d sess)

Done this 31st day of March 1947.

[SEAL] CHARLES F. BRANNAN,
Acting Secretary of Agriculture.

[F. R. Doc. 47-3225; Filed, Apr. 3, 1947; 8:46 a. m.]

TITLE 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Federal Security Administration

PART 141—TESTS AND METHODS OF ASSAY FOR ANTIBIOTIC DRUGS

PENICILLIN AND STREPTOMYCIN

By virtue of the authority vested in the Federal Security Administrator by the provisions of sections 507 and 701 (a) of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040, 1055, as amended by 59 Stat. 463 and Pub. Law 16, 80th Cong., 1st Sess.; 21 U. S. C. 371 (a); 21 U. S. C. Sup. 357) the regulations for tests and methods of assay of antibiotic drugs (11 F. R. 12123), as amended, are hereby repealed, and the following regulations are substituted therefor.

Sec.

141.1 Sodium penicillin, calcium penicillin, potassium penicillin; potency.
141.2 Sodium penicillin, calcium penicillin, potassium penicillin; sterility.
141.3 Sodium penicillin, calcium penicillin, potassium penicillin; pyrogens.
141.4 Sodium penicillin, calcium penicillin, potassium penicillin; toxicity.
141.5 Sodium penicillin, calcium penicillin, potassium penicillin; moisture, pH, clarity, crystallinity, and heat stability.
141.6 Sodium penicillin, calcium penicillin, potassium penicillin; penicillin X.

(Continued on p. 2217)

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FEDERAL REGISTER

Published daily, except Sundays, Mondays, and days following official Federal holidays, by the Division of the Federal Register, the National Archives, pursuant to the authority contained in the Federal Register Act, approved July 26, 1935 (49 Stat. 500, as amended; 44 U. S. C., ch. 8B), under regulations prescribed by the Administrative Committee, approved by the President. Distribution is made only by the Superintendent of Documents, Government Printing Office, Washington 25, D. C.

The regulatory material appearing herein is keyed to the Code of Federal Regulations, which is published, under 50 titles, pursuant to section 11 of the Federal Register Act, as amended June 19, 1937.

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CONTENTS—Continued

CODIFICATION GUIDE

A numerical list of the parts of the Code of Federal Regulations affected by documents published in this issue. Proposed rules, as opposed to final actions, are identified as such in parentheses.

[1] See Title 31, Part 131.

CODIFICATION GUIDE—Con.

AUTHORITY: §§ 141.1 to 141.106, inclusive, issued under sec. 507, 52 Stat. 1040 as amended by 59 Stat. 463 and Pub. Law 16, 80th Cong., 1st Sess.; 21 U. S. C. and Sup. 357.

§ 141.1 *Sodium penicillin, calcium penicillin, potassium penicillin; potency*—(a) *Cylinders (cups).* Use stainless steel cylinders with an outside diameter of 8 mm. (±0.1 mm.), an inside diameter of 6 mm. (±0.1 mm.), and a length of 10 mm. (±0.1 mm.).

(b) *Culture media.* Use ingredients that conform to the standards prescribed by the U. S. P. or N. F. (1) Make nutrient agar for the seed layer and for carryless steel cyliners with an outside diaming the test organism as follows:

Peptone	6.0 gm.
Pancreatic digest of casein	4.0 gm.
Yeast extract	3.0 gm.
Beef extract	1.5 gm.
Glucose	1.0 gm.
Agar	15.0 gm.
Distilled water, q. s	1,000.0 ml.

pH 6.5 to 6.6 after sterilization.

(2) Make nutrient agar for the base layer as follows:

Peptone	6.0 gm.
Yeast extract	3.0 gm.
Beef extract	1.5 gm.
Agar	15.0 gm.
Distilled water, q. s	1,000.0 ml.

pH 6.5 to 6.6 after sterilization.

(3) Make nutrient broth, for preparing an inoculum of the test organism, as follows:

Peptone	5.0 gm.
Yeast extract	1.5 gm.
Beef extract	1.5 gm.
Sodium chloride	3.5 gm.
Glucose	1.0 gm.
Dipotassium phosphate	3.68 gm.
Potassium dihydrogen phosphate	1.32 gm.
Distilled water, q. s	1,000.0 gm.

pH 7.0 after sterilization.

In lieu of preparing the media from the individual ingredients specified in paragraphs (b) (1), (2), and (3) of this section, they may be made from a dehydrated mixture which, when reconstituted with distilled water, has the same composition as such media. Minor modification of the individual ingredients specified in paragraphs (b) (1), (2), and (3) of this section are permissible if the resulting media possess growth promoting properties at least equal to the media described.

(c) *Working standard.* Keep the working standard (obtained from the Food and Drug Administration) in tightly stoppered vials, which in turn are kept in larger stoppered tubes containing anhydrous calcium sulfate, constantly in the refrigerator at 15° C. (59° F.) or below. Weigh out carefully in an atmosphere of 50 percent relative humidity or less between 4 and 5 mg. of the working standard and dilute with sterile 1% phosphate buffer (pH 6.0) to make a stock solution of any convenient concentration. Keep this solution at a temperature of about 10° C., and use for one day only. From this stock solution make appropriate working dilutions.

(d) *Preparation of sample.* Dissolve aseptically, in sterile distilled water, the sample to be tested to make an appropriate stock solution.

(e) *Preparation of plates.* Add 21 ml. of agar to each Petri dish (20 x 100 mm.). Distribute the agar evenly in the plates and allow it to harden. Use the plates the same day they are prepared. The test organism is Staphylococcus aureus (F. D. A. 209-P) or (9144) American Type Culture Collection. Maintain the test organism on agar slants and transfer to a fresh agar slant about once a week. Prepare an inoculum for the plates by transferring the culture from the agar slant into broth and incubate at 37° C. From 16 to 24 hours thereafter add 2.0 ml. of this broth culture to each 100 ml. of agar which has been melted and cooled to 48° C. Mix the culture and agar thoroughly and add 4 ml. to each of the plates containing the 21 ml. of the uninoculated agar. Tilt the plates back and forth to spread the inoculated agar evenly over the surface. Porcelain covers glazed on the outside are used. Place four cylinders on the agar surface so that they are at approximately 90° intervals on a 2.8 cm. radius. In so placing the cylinders drop them from a height of ½ inch, using a mechanical guide or device. A suspension of the test organism may be used in place of the broth culture described above in preparing the inoculum for the seeding of plates. Prepare such suspension as follows: Wash the organisms from an agar slant which has been incubated for 24 hours at 37° C. and stored for 24 hours at room temperature with 2.0 ml. of sterile physiological saline onto a large agar surface such as that provided by a Roux bottle containing 300 ml. of agar. Spread the suspension of organisms over the entire agar surface with the aid of sterile glass beads. Incubate 24 hours at 37° C. and store for 24 hours at room temperature. Wash the resulting growth from the agar surface with about 50 ml. of sterile physiological saline. Standardize this suspension by determining the dilution which will permit 20% light transmission through a filter at 6500 Ångstrom units in a photoelectric colorimeter. Add 1.5 to 2.0 ml. of this resulting dilution to each 100 ml. of agar which has been melted and cooled to 43° C. to prepare the inoculum for the plates. The suspension may be used for one week.

(f) *Assay.* Use four plates for each sample. Fill one cylinder on each plate with a 1.0 unit per ml. dilution, and one with a 0.25 unit per ml. dilution, of the working standard. Add the estimated dilutions of 1.0 unit per ml. and 0.25 unit per ml. of the sample under test to the remaining 2 cylinders on each plate. Carefully place the plates in racks and incubate 16 to 18 hours at 37° C. After incubation measure the diameter of each circle of inhibition to the nearest 0.5 mm. using a colony counter with a mm. scale etched into the supporting glass over the light source. Other measuring devices of equal accuracy may be used.

(g) *Estimation of potency and error.* (1) Use the accompanying chart (Chart 1) and nomograph (Chart 2) for estimating the potency and its error. To use the chart for estimating potency two values, namely, V and W, are required. For each plate calculate two values.

$$v=(u_L+u_H)-(s_L+s_H)$$

and

$$w=(u_H+s_H)-(u_L+s_L)$$

where s_H and s_L are the diameters of the zones of inhibition in mm. of the 1.0 unit and 0.25 unit dilutions of the standard, respectively, and u_H and u_L refer similarly to the corresponding dilutions of the sample under test. The value V is the sum of the v values for all plates and W is the sum of the w values for all plates. To estimate the potency locate the point on the chart corresponding to the values of V and W, and the potency can be read from the radial lines on the chart.

(2) The error of the assay is estimated by using the nomograph which requires five values, namely, the potency, V, W, Rv, and Rw. Rv (the range of the v's) is the highest value of v minus the lowest value of v obtained from the individual plates. Similarly, Rw is the difference between the highest and lowest w values. After obtaining these five values, connect with a straight edge the points corresponding to v and w on the respective scales on the right side of the nomograph. Mark with a pin or sharp-pointed pencil the intersection of the straightedge and the diagonal line of the nomograph. Move the straightedge so that it connects the value of Rw on its scale and the diagonal line at the point of the pin. The value for Q is thus determined by the scale value where the straightedge crosses the line labeled "Q". T is obtained by adding the squares of Q and Rv. On the left side of the chart con-

nect the values of T and W with the straightedge and read the value of the ratio (error of assay-potency) where the straightedge intersects the scale of values for the ratio. This value multiplied by the potency equals the percentage error of the assay. The error of the assay calculated here estimates only how closely one assayist can check himself on any given set of dilutions of unknown and standard. It does not include any errors of weighing or errors due to variations in materials or subdivisions of a lot of penicillin.

The chart for determining potency should not be used for determinations of potency lower than 50% or higher than 150% of the standard. If the potency lies outside these limits, the assay should be repeated using a higher or lower dilution. The radial lines on the

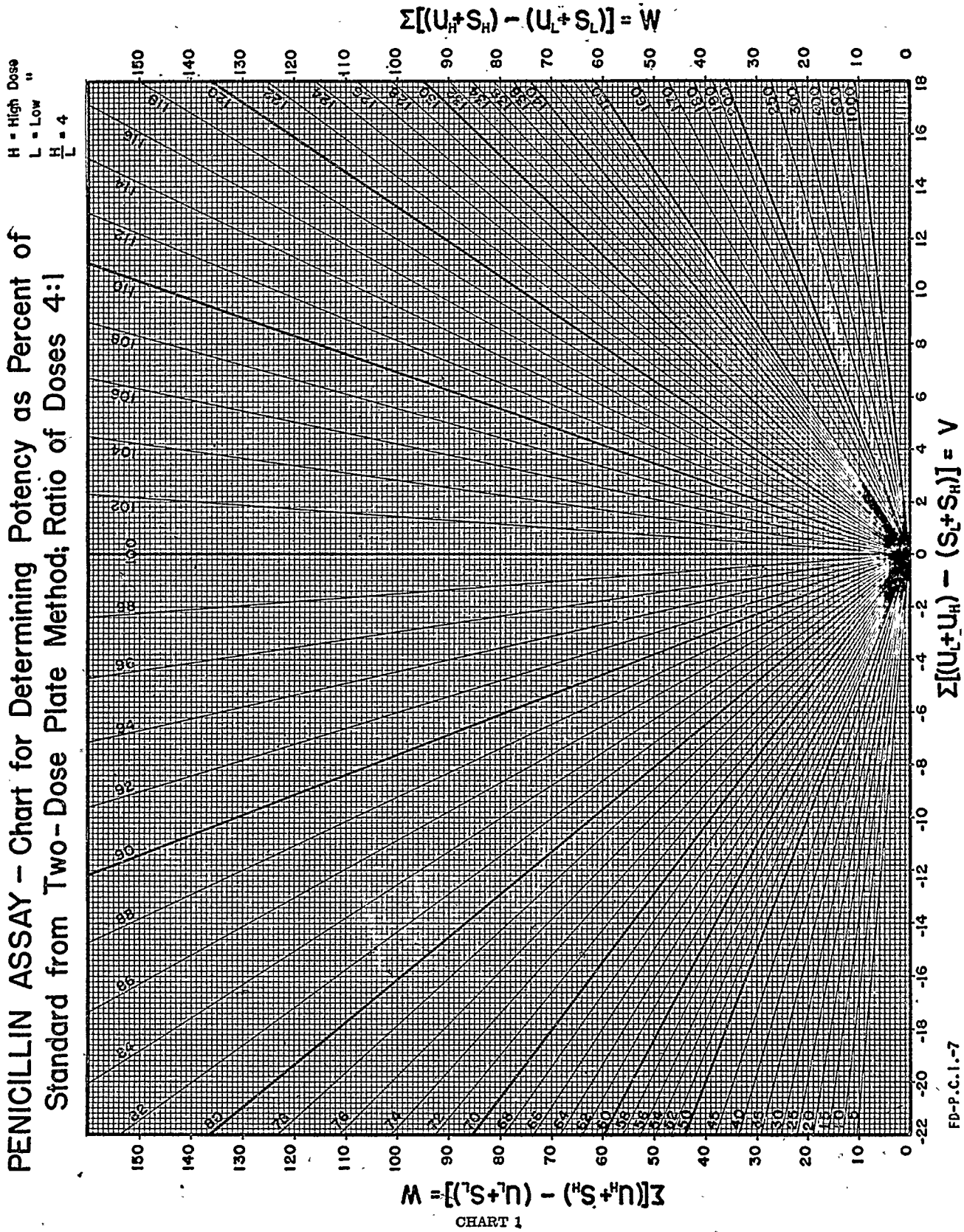

CHART 1

PENICILLIN ASSAY

Nomographs for estimating Error of Assay

(2 dose, 4 plate method. Ratio of doses 4:1)

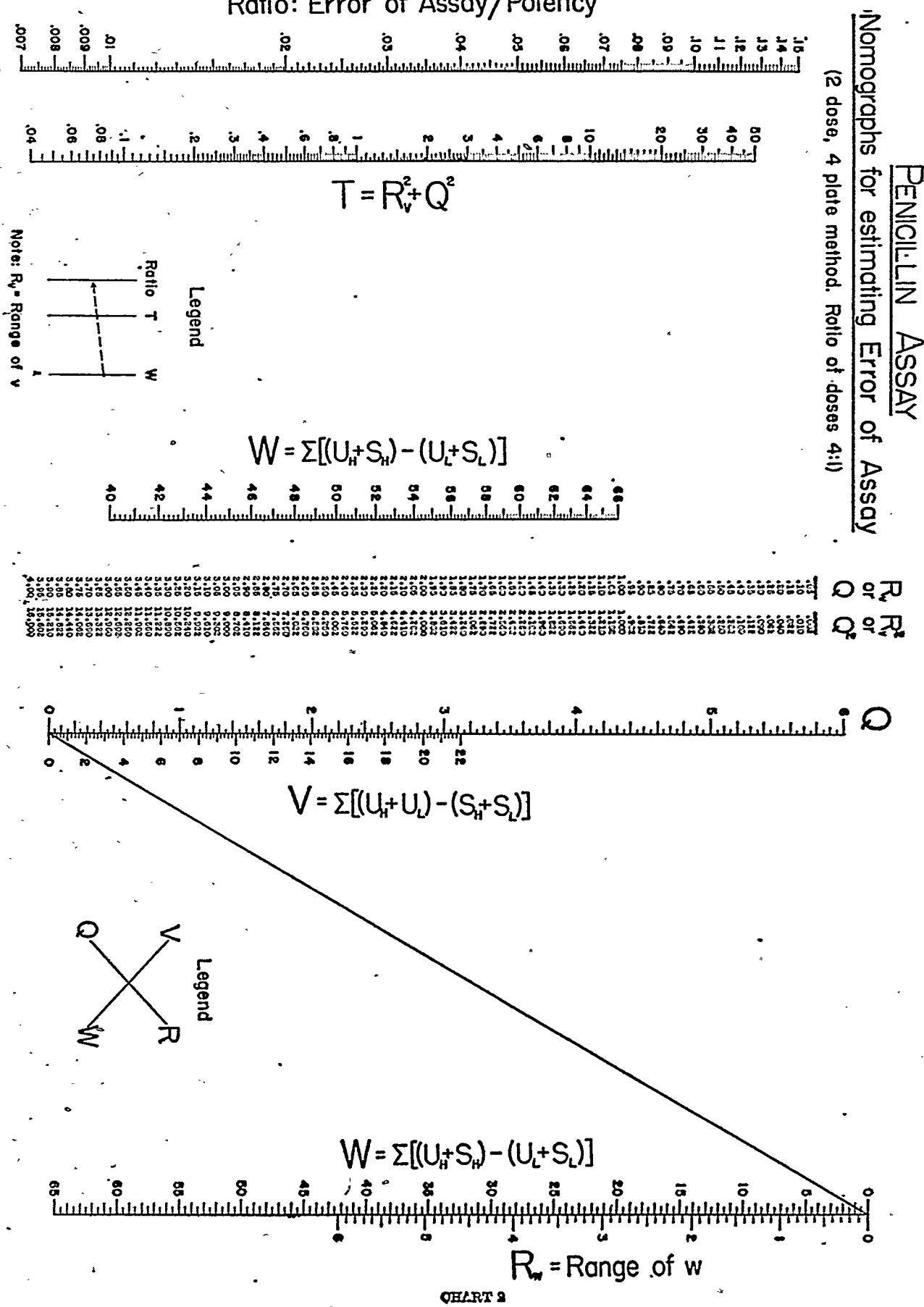

CHART 2

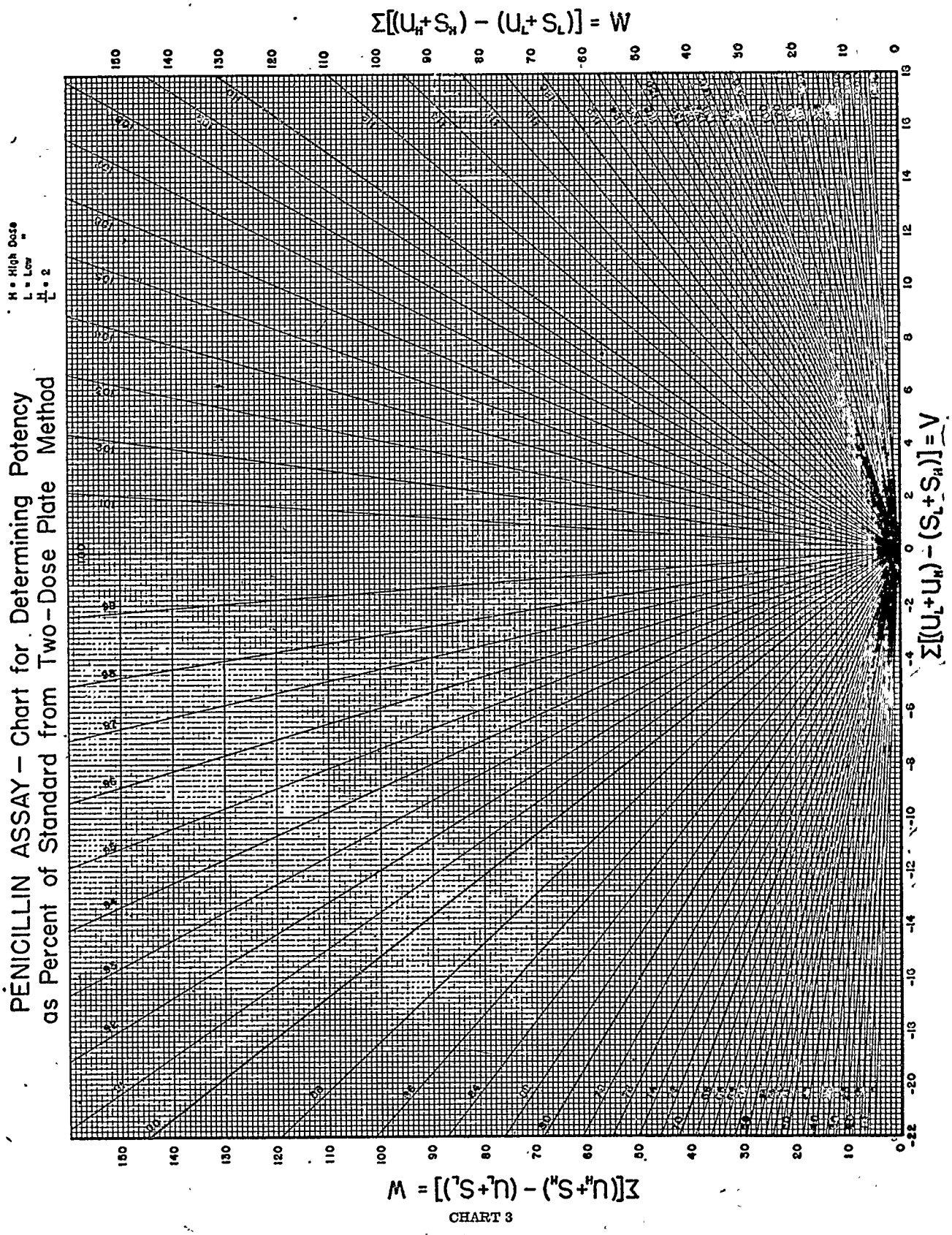
PENICILLIN ASSAY — Chart for Determining Potency as Percent of Standard from Two-Dose Plate Method
H = High Dose
L = Low "
H/L = 2
Σ[(U_H+S_H) − (U_L+S_L)] = W
Σ[(U_L+U_H) − (S_L+S_H)] = V

CHART 3

chart beyond these limits permit a rough estimation of potency from as low as 5% to as high as 1,000% when low values of W are found. If the value of V or W falls outside the limits of the chart, divide both V and W by the same proper number to bring them into the range of the chart and read the potency from the radial lines as before. If 11.4 Rw is greater than W, the slope of the assay does not differ significantly from zero and the assay is invalid. (The figure 11.4 was obtained by use of Student's "t" test for determining the significance of a slope.)

In certain laboratories it has been noted that with the 4 to 1 ratio, involving concentrations of 0.25 unit for the low dose, the zone of inhibition given by this dose may either be too small for accurate reading or have edges which are poorly defined. In order to permit the use of a higher concentration of penicillin for the low dose the third of the attached charts (Chart 3) may be used in assays in which the ratio of doses is 2 to 1, i. e., the high dose (*sH*) is twice the low dose (*sL*). As in the preceding chart (Chart 1), if the potency lies outside the limits of 50% to 150% the assay should be repeated, using a lower or higher dilution. The potencies beyond these limits are to be used for rough estimation purposes only. These extensions can also be used for four (or more) plate assays if both V and W are divided by the same proper number to bring them into the range of the chart. The error of the assay using the ratio of doses 2 to 1 is estimated by using the nomograph (Chart 2) in the same manner as described for the 4 to 1 ratio of doses. However, the resultant error of the assay derived in this manner must be divided by 2 to give the correct error of the assay for the 2 to 1 ratio of doses.

(h) The potency of a sample may also be determined by the standard curve technique using a single dose of standard and unknown.

Dilute the sample to be tested to 1.0 unit per ml. (estimated) in 1% phosphate buffer pH 6.0. Place six cylinders on the inoculated agar surface so that they are at approximately 60° intervals on a 2.8 cm. radius. Use three plates for each sample. Fill 3 cylinders on each plate with the 1.0 unit/ml. standard and 3 cylinders with the 1.0 unit/ml. (estimated) sample, alternating standard and sample. Incubate the plates for 16 to 18 hours at 37° C. and measure the diameter of each circle of inhibition. At the same time prepare a standard curve using concentrations of the standard of 0.6, 0.7, 0.8, 0.9, 1.0, 1.1, 1.2, 1.3, 1.4, and 1.5 units/ml. in sterile 1% phosphate buffer pH 6.0. Use three plates for the determination of each point on the curve, a total of 27 plates. On each of three plates fill 3 cylinders with the 1.0 unit/ml. standard and the other 3 cylinders with the concentration under test. Thus there will be 81 one unit determinations and 9 determinations for each of the other points on the curve. After the plates have incubated read the diameters of the circles of inhibition. Average the readings of 1.0 unit/ml. concentration and the readings of the point tested for each set of 3 plates and average also all 81 readings of the 1.0 unit/ml. concentration. The average of the 81 readings of the 1.0 unit/ml. concentration is the correction point for the curve. Correct the average value obtained for each point to the figure it would be if the 1.0 unit/ml. reading for that set of three plates were the same as the correction point. Thus, if in correcting the 0.8 unit concentration, the average of the 81 readings of the 1.0 unit concentration is 20.0 mm., and the average of the 1.0 unit concentration of this set of 3 plates is 19.8 mm., the correction is 0.2 mm. If the average reading of the 0.8 unit concentration of these same 3 plates is 19.0 mm. the corrected value is then 19.2 mm. Plot these corrected values including the average of the 1.0 unit/ml. concentration on 2 cycle semilog paper using the concentration in units per ml. as the ordinate (the logarithmic scale) and the diameter of the zone of inhibition as the abscissa. Draw the standard curve through these points. The 10 points selected to determine the curve are arbitrary and should be so chosen that the limits of the curve will fill the needs of the laboratory. However the potency of the sample under test should fall in the interval of from 60% to 150% of the correction point of the standard curve.

To estimate the potency of the sample average the zone readings of the standard and the zone readings of the sample on the three plates used. If the sample gives a larger average zone size than the average of the standard, add the difference between them to the 1.0 unit zone on the standard curve. If the average sample value is lower than the standard value, subtract the difference between them from the 1.0 unit value on the curve. From the curve read the potencies corresponding to these corrected values of zone sizes.

(i) The potency of sodium penicillin, calcium penicillin, and potassium penicillin is satisfactory when assayed by the methods described in this section if the immediate containers are represented to contain:

200,000 units or less and contain 85% or more of the number of units so represented;

More than 200,000 units and contain 90% or more of the units so represented.

§ 141.2 *Sodium penicillin, calcium penicillin, potassium penicillin; sterility*—(a) *Culture medium.* Use U. S. P. fluid thioglycollate medium I or a dehydrated mixture which, when reconstituted with distilled water, has the same composition as such medium and has growth-promoting, buffering, and oxygen tension controlling properties equal to or better than those of such medium.

In the preparation of the medium, from either the individual ingredients or any dehydrated mixture, avoid contamination with calcium.

(b) *Conduct of test.* Dissolve the sample to be tested in sufficient sterile, freshly prepared solution of 1:300 hydroxylamine hydrochloride, adjusted to pH 6.0 with sodium hydroxide, so that each ml. contains approximately 5,000 to 10,000 units. Shake vigorously. Let stand one hour, transfer 1 ml. aseptically to each of four tubes containing 15 ml. of fluid thioglycollate medium. Inoculate one of these tubes with 1.0 ml. of a 1:1000 dilution of an 18 to 24 hour broth culture of S. aureus 209–P, and incubate all four tubes for four days at 37° C. The inoculated tube should show growth at the end of four days; if so and no other tube shows growth, the sample is sterile.

§ 141.3 *Sodium penicillin, calcium penicillin, potassium penicillin; pyrogens*—(a) *Test animal.* Use healthy rabbits, weighing 1,500 gm. or more, which have been maintained for at least one week on a uniform, unrestricted diet and have not lost weight during this period. For subsequent tests, animals utilized for previous tests may be used after a rest period of not less than two days. Use a clinical rectal thermometer after it has been tested in a rabbit to determine the time required to reach maximum temperature. (Other recording devices of equal sensitivity are acceptable.) Insert the thermometer or other recording device beyond the internal sphincter and allow it to remain a sufficient time to reach maximum temperature as determined above. Make four rectal temperature readings on each of the animals to be used in the test at 2-hour intervals, 1 to 3 days before such use (this may be omitted for any animal that has been used in such tests during a preceding period of two weeks). House the test animals in individual cages and protect them from disturbances likely to cause excitement. Exercise particular care to avoid exciting the animals on the day of taking the control temperatures and on the test day. Maintain the animals in an environment of uniform temperature (±5° F.) at all times.

(b) *Conduct of test.* Heat all syringes and needles to be used in a muffle furnace at 250° C. for not less than 30 minutes to render them pyrogen-free and sterile. Perform the test in a room held at the same temperature as that in which the animals are housed. During the test restrain the animals in individual stocks. Withhold all food from one hour before the first temperature reading until after the final reading of the day. Take a control temperature reading not more than 15 minutes after the animal is removed from the cage. Use three animals for each test, but do not use those with control temperatures of 38.8° C. or under and 39.9° C. or over. Dilute the sample with pyrogen-free, sterile, distilled water to a concentration of 2,000 units per ml. and warm to approximately 37° C. Inject 2,000 units (estimated) per kg. of rabbit intravenously through an ear vein within 15 minutes subsequent to the control temperature reading. Read temperatures one hour after injection and each hour thereafter until three readings have been made. The sample is non-pyrogenic if when so tested no animal shows a rise in any of the temperature readings, after injection, of 0.6° C. or more above the control temperature of such animal. If only one animal shows such a rise in temperature, or if the sum of the

temperature rises of the three animals exceeds 1.4° C., repeat the test on five additional animals. The sample is nonpyrogenic if not more than one of these five animals shows a rise in temperature of 0.6° C. or more above the control temperature of such animal.

§ 141.4 *Sodium penicillin, calcium penicillin, potassium penicillin; toxicity.* Inject intravenously each of five mice, within the weight range of 18 to 25 grams, with 0.5 ml. of a solution of the sample prepared by diluting with sterile distilled water to approximately 4,000 units per ml. The injection should be made over a period of not more than 5 seconds. If no animal dies within 48 hours, the sample is nontoxic. If one or more animals die within 48 hours, repeat the test with five unused mice weighing 20 grams (±0.5 gm.) each; if all animals survive the repeat test, the sample is nontoxic.

§ 141.5 *Sodium penicillin, calcium penicillin, potassium penicillin*—(a) *Moisture.* In an atmosphere of about 10% relative humidity, transfer 30 to 50 mgm. of the finely powdered sample to a tared weighing bottle or weighing tube equipped with a capillary-tube stopper, the capillary having an inside diameter of 0.20 to 0.25 mm. Weigh the bottle or tube and place it in a vacuum oven, without removing the stopper and dry at a temperature of 60° C. and a pressure of 5 mm. of mercury or less for three hours. At the end of the drying period, fill the vacuum oven with air dried by bubbling it through sulfuric acid; place weighing bottles or tubes in a desiccator over phosphorous pentoxide, allow to cool to room temperature, and reweigh. Divide the loss in weight by the weight of the sample and multiply by 100 to obtain the percentage of moisture.

(b) *pH.* Dilute the sample to be tested with carbon dioxide-free distilled water so that the resulting solution contains 5,000 to 10,000 units per ml. Determine the pH of this solution at 25°C. using a pH meter equipped with a glass and a calomel electrode.

(c) *Clarity.* Add to the sample by means of a thoroughly cleansed hypodermic needle and syringe enough of the diluent to produce a solution containing 5,000 to 10,000 units per ml. The resulting solution must be substantially free of any turbidity or undissolved material which can be detected readily without accessory magnification (except such optical correction as may be required to establish normal vision), when the solution is examined against a black and white background with a bright light from a 100 watt lamp or equivalent lighting after holding at 15° C. (59° F.) or less for 48 hours.

(d) *Microscopical test for crystallinity of sodium penicillin and potassium penicillin.* Mount in mineral oil and examine by means of a polarizing microscope. Crystalline penicillin shows resolvable particles which reveal the phenomena of birefringence (interference colors) and extinction positions on revolving the microscope stage. Crystalline penicillin also reveals diagnostic refractive indices when examined by the immersion method.

(e) *Stability of crystalline penicillin.* Store a weighed sample (approximately 30 mg.) of crystalline penicillin in an unstoppered 50 ml. Erlenmeyer flash for 4 days in an electric oven at 100° C. ±1°. At the end of this period it does not show a loss of more than 10% of its original potency when determined as follows: Dilute a weighed sample (approximately 30 mg.) with 1% phosphate buffer at pH 6.0 to a concentration of approximately 1.2 mg./ml. (2,000 units/ml.). Add 2.0 ml. aliquots to each of two 125 ml. glass stoppered Erlenmeyer or iodine flasks. To one add 2.0 ml. of 1N NaOH and allow to stand at room temperature for 15 minutes. At the end of this time add 2.0 ml. of 1.2N HCl and add 10.0 ml. of 0.01N I_2 (prepared from 0.1N I_2 U. S. P.). (Equal volumes of 1N NaOH and 1.2N HCl when mixed give pH 1.0). After 15 minutes titrate the excess iodine using 0.01N $Na_2S_2O_3$ (prepared from 0.1N $Na_2S_2O_3$) standardized accurately against potassium iodate. Toward the end of the titration add approximately 5 ml. of CCl_4. Continue the titration by the addition of 0.01 to 0.02 ml. portions of the 0.01N $Na_2S_2O_3$ shaking vigorously after each addition. The end-point is reached when the CCl_4 layer becomes colorless. To the second flask add 10 ml. of the 0.01N I_2 and titrate immediately with 0.01N $Na_2S_2O_3$ for the blank determination. Regard the difference in titers divided by 2.52 as the milligrams of penicillin sodium salt.

$$\text{Percent loss of potency} = \frac{\text{Original assay} - \text{Assay after 4 days at 100° C} \times 100}{\text{Original assay}}$$

(f) *Crystalline penicillin G*—(1) *Reagents.* The reagents described in subdivisions (i), (ii), and (iii) of this subparagraph are freshly prepared every three days and are of such quality that when used in this procedure with a known penicillin G not less than 97 percent of penicillin G is recovered.

(i) *Amyl acetate solution.* Saturate the amyl acetate with the N-ethyl piperidine salt of penicillin G by adding 2 mg. of the salt for each 1 ml. of the solvent. Cool this solution to 0° to 8° C. and filter by drawing it through a plug of cotton on the tip of a pipette immediately before use.

(ii) *Acetone solution.* Saturate reagent grade acetone with the N-ethyl piperidine salt of penicillin G using 3 mg. of salt for each 1 ml. of acetone. Cool this solution to 0° to 8° C. and filter by drawing it through a plug of cotton on the tip of a pipette immediately before use.

(iii) *N-ethyl piperidine solution.* N-ethyl piperidine should be stored in brown bottles in a refrigerator. Dilute 1.0 ml. of this reagent with 4.0 ml. of amyl acetate. Saturate this solution with the N-ethyl piperidine salt of penicillin G using about 3 mg. of the salt for each 1.0 ml. of solution. Cool this solution to 0° to 8° C. and filter by drawing it through a plug of cotton on the tip of a pipette immediately before use.

(iv) *Phosphoric acid solution.* Prepare by dissolving 1.0 ml. of reagent grade phosphoric acid (85%) in 4.0 ml. of water. Cool to 0° to 8° C. and shake before using.

(v) *Sodium sulfate.* Use powdered anhydrous reagent grade sodium sulfate.

(2) *Procedure.* Add 4 ml. of distilled water for each 200,000 units or 120 mg. of the sample to be tested. Pipette a 2.0 ml. aliquot into a glass test tube of about 10 ml. capacity and cool to 0° to 5° C. Add 2 ml. of the amyl acetate solution and 0.5 ml. of the phosphoric acid solution, stopper and shake vigorously for approximately 15 seconds. Centrifuge to obtain a clear separation of the two layers (approximately 20 seconds). After centrifuging remove as much of the amyl acetate layer as possible (usually about 1.7 to 1.8 ml.) with a 2 ml. hypodermic syringe equipped with a suitable needle. Place about 0.1 gm. of the sodium sulfate in a micro filter funnel (approximately 10 mm. diameter) having a fritted glass disc of medium porosity and add the amyl acetate solution from the hypodermic syringe. Collect the filtrate by suction in a small test tube which has been placed in a suction flask. Surround suction flask with cracked ice. Pipette a 1.0 ml. aliquot of the amyl acetate filtrate into a tared flat bottom glass tube (approximately 15 x 50 mm.) containing 1.0 ml. of the acetone solution and 0.5 ml. of the N-ethyl piperidine solution. The time elapsing between acidification and the addition of the filtrate to the above reagents should not be more than three minutes. Place the glass tube containing this mixture in a large weighing bottle, stopper the bottle and allow to stand for not less than 2 hours in a refrigerator at 0° to 8° C. Remove the liquid from the precipitate by means of a tared micro filter stick and wash with a total of 1 ml. of the acetone solution adding the latter by means of a hypodermic syringe equipped with a fine needle. Place the filter stick inside the glass tube, dry under vacuum at room temperature for not less than one hour, and weigh. (Save all N-ethyl piperdine penicillin G residues for saturating reagents). Remove a 1.0 ml. aliquot of the original aqueous penicillin solution and dilute to 25.0 ml. (approximately 2000 units per ml.) with 1% phosphate buffer at pH 6.0. Using 2.0 ml. aliquots of this dilution, determine the amount of penicillin in the original solution in mg./ml. by the iodometric assay procedure described in paragraph (e) of this section.

$$\text{Percent of penicillin G} = \frac{\text{Wt. in mg. N-ethyl piperidine penicillin precipitate} \times 159.3}{\text{Milligrams of penicillin in 2.0 ml. of original solution}}$$

Determine the potency of crystalline penicillin G by the method prescribed in paragraph (e) of this section.

(g) *Penicillin K content.* Determine the content of penicillin K by the following method:

Dilute a weighed sample or the contents of a vial with 0.3 M phosphate (Na_2HPO_4 and KH_2PO_4) buffer pH 6.0 to give a solution containing approximately 1,000 units/ml. In the case of calcium penicillin where a precipitate of calcium phosphate occurs, remove the precipitate by filtration and use the clear filtrate. Place a 15.0 ml. aliquot of this solution in a 125 ml. separatory funnel, add 30.0 ml. of chloroform U. S. P. and shake for one minute. (Carry out all operations at room temperature.) Allow the mixture to stand with occasional swirling to settle the droplets of chloroform until the top layer is clear (usually about 10 minutes). Draw off all but about 2 ml. of the lower chloroform layer thru a small pledget of cotton into a glass stoppered flask. Take a 4.0 ml. aliquot of the original solution, a 4.0 ml. aliquot of the buffer solution remaining in the separatory funnel and a 10.0 ml. aliquot of the chloroform solution and determine the mg./ml. of penicillin in each by the iodometric assay procedure described in paragraph (e) of this section using 4.0 ml. of the 1N NaOH and 4.0 ml. of the 1.2N HCl for each of the above aliquots. Make blank determinations on the same size aliquots. Calculate the percent penicillin in the buffer layer and in the chloroform layer as compared to the original solution. The sum of these percentages should be 100%±2%. The percent penicillin K= (96.92+% in chloroform—% in buffer) ×1.67. (The factors in the above formula are based on distribution coefficients of penicillin K and G between chloroform and aqueous phosphate buffer at pH 6.0.)

§ 141.6 *Sodium penicillin, calcium penicillin, potassium penicillin; penicillin X.* Dissolve the contents of a 100,000 unit ampul in about 20 ml. of ice cold distilled water. Transfer quantitatively to a 100 ml. volumetric flask, rinsing the ampul with small portions of ice cold water and make to 100 ml. Pipette a 50.0 ml. aliquot into a 125 ml. separatory funnel, then add 50.0 ml. of cold chloroform and shake the mixture. Add an amount of approximately 1N H_2SO_4 to bring the pH of the aqueous layer to 2.0. (The amount of 1N H_2SO_4 to be added is calculated by titrating a separate 5.0 ml. aliquot of the 100 ml. dilution to pH 2.0 using a suitable pH meter.) Shake the mixture vigorously for one minute. Allow the layers to separate and filter the chloroform through a small pledget of cotton, moistened with chloroform, into a second 125 ml. separatory funnel. Shake the acid aqueous solution with a second 50.0 ml. of cold chloroform and, when the layers have separated, withdraw the chloroform through the same filter into the second separatory funnel. Immediately neutralize the acid aqueous solution, containing the penicillin X, with 0.1N NaOH to pH 6.5 to 7.0 using the pH meter and make to 100 ml. with water. Make appropriate dilutions in 1% phosphate buffer at pH 6.0 and assay as directed in § 141.1 (f) or (h). Shake the combined chloroform extracts, containing any penicillin G, etc., with small successive portions of cold $NaHCO_3$ solution (0.1%), until the combined $NaHCO_3$ extracts give a pH of 7.0, and make to 100 ml. with water. Make the proper estimated dilutions in 1% phosphate buffer at pH 6.0. Assay these last dilutions as directed in § 141.1 (f) or (h). The potency of the penicillin X fraction plus potency of the penicillin G, etc., fraction should approximate that of the potency of the original solution. All of the above extractions should be carried out in a cold room.

§ 141.7 *Penicillin in oil and wax*—(a) *Potency.* Proceed as directed in § 141.1 except paragraph (i) thereof and, in lieu of the directions in paragraph (d), of § 141.1, prepared sample as follows:

Liquefy the sample by warming, thoroughly mix, and withdraw 1.0 ml. using a sterile syringe equipped with an 18 gauge needle. Transfer to a separatory funnel containing approximately 50 ml. of peroxide-free ether. Shake the separatory funnel vigorously to bring about complete mixing of the material with the ether. Shake with a 25 ml. portion of 1% phosphate buffer at pH 6.0. Remove the buffer layer and repeat the extraction with three 25-ml. quantities of buffer. Combine the extracts and make the proper estimated dilutions in 1% phosphate buffer at pH 6.0. If the label represents the potency of the penicillin in oil and wax as 200,000 units per ml. or less, it is satisfactory if it is 85% or more of the potency so represented; if represented as more than 200,000 units per ml., it is satisfactory if it is 90% or more of the potency so represented.

(b) *Sterility.* Proceed as directed in § 141.2, except that sufficient penicillinase is added to the thioglycollate medium to inactive the penicillin added in the test and, in lieu of the directions in the first three sentences of paragraph (b) of § 141.2, proceed as follows:

Liquefy the sample by warming and add aseptically approximately 1.0 ml. to 9.0 ml. of sterile warm cottonseed oil. Shake vigorously. Transfer 1.0 ml. aseptically to each of four tubes containing 15 ml. of fluid thioglycollate medium with added penicillinase.

(c) *Moisture.* Weigh 1.0 (±0.2) gm. of the sample into a shallow moisture dish. Dry to constant weight in a vacuum oven at a uniform temperature not less than 20° C. nor more than 25° C. above the boiling point of water at the working pressure, which does not exceed 100 mm. of mercury. Constant weight is attained when successive dryings for 1 hour periods show additional loss of not more than 0.1%. Cool the sample in an efficient desiccator for 30 minutes before reweighing.

§ 141.8 *Penicillin ointment*—(a) *Potency.* Proceed as directed in § 141.1, except paragraph (i) thereof, and, in lieu of the directions in paragraph (d) of § 141.1 prepare the sample as follows:

Accurately weigh the tube and contents and squeeze 0.5 to 1.0 gm. into a separatory funnel containing approximately 50 ml. of peroxide-free ether. Reweigh the tube to obtain weight of ointment used in the test. Shake ointment and ether until homogeneous. Shake with a 25 ml. portion of 1% phosphate buffer at pH 6.0. Remove the buffer layer and repeat the extraction with three 25 ml. quantities of buffer. Combine the extracts and make the proper estimated dilutions in 1% phosphate buffer at pH 6.0. The potency of penicillin ointment is satisfactory if it contains not less than 85% of the number of units per gram it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141.7 (c).

(c) *Microorganism count.* Prepare nutrient agar as directed in § 141.1 (b) (1). Cool to approximately 48° C. and add sufficient sterile penicillinase solution so that each 20 ml. will contain enough to completely inactivate the amount of penicillin contained in the sample under test. Pour 20 ml. of the agar-penicillinase mixture into Petri dishes and allow to harden. The Petri dishes are warmed to 37° C. just before use. Accurately weigh the tube and contents, place in incubator at 37° C. for one hour, then squeeze from 0.1 to 0.5 gm. of the ointment onto the agar surface. Reweight tube to obtain weight of ointment used in test. Spread the ointment evenly over the surface of the agar with a sterile glass rod, invert, and place in a 37° C. incubator for 48 hours. Count the number of colonies appearing on the plates and calculate therefrom the number of viable microrganisms per gm. of ointment.

§ 141.9 *Tablets buffered penicillin*—(a) *Potency.* Proceed as directed in § 141.1, except paragraph (i) thereof and, in lieu of the directions in paragraph (d) of § 141.1, prepare sample as follows:

Place 12 tablets in a mortar and add approximately 20 ml. of 1% phosphate buffer at pH 6.0. Disintegrate the tablets by grinding with a pestle. Transfer with the aid of small portions of the buffer solution to a 500 ml. volumetric flask and make to 500 ml. by adding sufficient phosphate buffer. Make the proper estimated dilutions in 1% phosphate buffer at pH 6.0. The average potency of tablets buffered penicillin is satisfactory if it contains not less than 85% of the number of units per tablet it is represented to contain.

(b) *Moisture.* Proceed as described in § 141.5 (a).

§ 141.11 *Penicillin with aluminum hydroxide gel*—(a) *Sodium penicillin, calcium penicillin, potassium penicillin.* Proceed as directed in §§ 141.1, 141.2, 141.4, and 141.5 (a) and (b), and if crystalline penicillin, (d), (e), and (g), and if crystalline penicillin G, (f).

(b) *Aluminum hydroxide gel.* Thoroughly shake the aluminum hydroxide gel and transfer aseptically 1.0 and 0.1 ml. portions in triplicate to sterile Petri dishes. Pour into each Petri dish 20 ml. of nutrient agar, described in § 141.1 (b) (1), which has been melted and cooled to 48° C. Thoroughly mix the aluminum hydroxide and melted agar. Allow the agar to solidify, invert the Petri dishes, and incubate for 48 hours at 37° C. Count the number of colonies appearing on the plates and calculate therefrom the number of viable bacteria per ml. of the aluminum hydroxide gel.

§ 141.12 *Penicillin troches*—(a) *Potency.* Proceed as directed in § 141.1 ex-

cept paragarph (i) thereof and, in lieu of the directions in paragraph (d) of § 141.1, prepare sample as follows:

If the troche does not contain a masticatory substance, proceed as directed in § 141.9 (a). If the troche contains a masticatory substance, place five troches in a separatory funnel containing 75 ml. of n-hexane; shake until the troches are dissolved. Shake with a 25 ml. portion of 1% phosphate buffer at pH 6.0. Remove the buffer layer and repeat the extraction with three 25 ml. quantities of buffer. Combine the extracts and make the proper estimated dilutions in 1% phosphate buffer at pH 6.0. The average potency of the troche is satisfactory if it contains not less than 85% of the number of units per troche it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141.5 (a) or if it contains a masticatory substance as directed in § 141.7 (c).

§ 141.13 *Penicillin dental cones*—(a) *Potency.* Proceed as directed in § 141.1, except paragraph (i) thereof and, in lieu of the directions in paragraph (d) of § 141.1, prepare sample using 5 cones as directed in § 141.9 (a). The average potency of the cone is satisfactory if it contains not less than 85% of the number of units per cone it is represented to contain.

(b) *Microorganism count.* Accurately weigh from 3 to 5 cones in a small test tube and add sufficient sterile penicillinase, contained in a total volume of 2 ml. to inactivate the penicillin present. Let stand one hour. Thoroughly shake the mixture and transfer, aseptically, the entire amount to a sterile Petri dish. Pour into the Petri dish 20 ml. of nutrient agar, described in § 141.1 (b) (1) which has been melted and cooled to 48° C. Thoroughly mix, allow the agar to solidify, invert the Petri dish, and incubate for 48 hours at 37° C. Count the number of colonies appearing on the plates and calculate therefrom the number of viable microorganisms per gm.

(c) *Moisture.* Proceed as directed in § 141.5 (a).

§ 141.14 *Penicillin with vasoconstrictor*—(a) *Calcium Penicillin.* Proceed as directed in §§ 141.1, 141.2, 141.3, 141.4, and 141.5 (a), (b), and (c).

§ 141.15 *Penicillin for surface application*—(a) *Potency.* Proceed as directed in § 141.9 (a) using the contents of 12 immediate containers.

(b) *Microorganism count.* Accurately weigh approximately 0.5 gm. in a small test tube and add sufficient sterile penicillinase contained in a total volume of 2 ml. to inactivate the penicillin present. Let stand 1 hour. Thoroughly shake the mixture and transfer, aseptically, the entire amount to a sterile Petri dish. Pour into the Petri dish 20 ml. of nutrient agar, described in § 141.1 (b) (1), which has been melted and cooled to 48° C. Thoroughly mix, allow the agar to solidify, invert the Petri dish, and incubate for 48 hours at 37° C. Count the number of colonies appearing on the plates and calculate therefrom the number of viable microorganisms per gm.

(c) *Moisture.* Proceed as directed in § 141.5 (a).

§ 141.16 *Tablets alum precipitated penicillin*—(a) *Potency.* Proceed as directed in § 141.9 (a).

(b) *Moisture.* Proceed as directed in § 141.5 (a).

§ 141.17 *Penicillin sulfonamide powder*—(a) *Potency.* Proceed as directed in § 141.9 (a) using the contents of 12 immediate containers.

(b) *Moisture.* Proceed as directed in § 141.5 (a).

(c) *Sterility.* Proceed as directed in § 141.2 except that sufficient penicillinase is added to the thioglycollate medium to inactivate the penicillin added in the test and in lieu of the directions in the first three sentences of paragraph (b) of § 141.2 proceed as follows:

Suspend aseptically approximately one-fourth of the sample to be tested (about 0.5 gm.) into each of four tubes containing 15 ml. of fluid thioglycollate medium with added penicillinase.

§ 141.18 *Penicillin vaginal suppositories*—(a) *Potency.* Proceed as directed in § 141.1 except paragraph (i) thereof and in lieu of the directions in paragraph (d) of § 147.1 prepare sample as follows:

Place 5 suppositories in a separatory funnel containing 150 ml. of peroxide-free ether. Shake the separatory funnel vigorously to bring about complete mixing of the material with the ether. Shake with a 25 ml. portion of 1% phosphate buffer at pH 6.0. Remove the buffer layer and repeat the extraction with three 25 ml. quantities of buffer. Combine all extracts and make the proper estimated dilutions in 1% phosphate buffer at pH 6.0. The average potency of the suppository is satisfactory if it contains not less than 85% of the number of units it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141.7 (c) using one suppository.

(c) *Microorganism count.* Use four suppositories and place approximately one fourth of each into each of four sterile, tared test tubes. Determine weight of sample in each tube. Melt at 37° C. and add sufficient penicillinase to inactivate the penicillin in the sample. Mix thoroughly. Incubate for one hour at 37° C. Mix thoroughly and transfer the contents of each tube to 25 ml. of nutrient agar prepared as directed in § 141.1 (b) (1) cooled to approximately 48° C. Mix thoroughly and pour into sterile Petri dishes. Allow to harden, invert and incubate at 37° C. for 48 hours. Count the number of colonies appearing on the Petri dish and calculate therefrom the number of viable microorganisms per gm. of suppository.

§ 141.19 *Buffered crystalline penicillin.* Proceed as directed in §§ 141.1, 141.2, 141.3, 141.4, 141.5 and 141.6.

§ 141.20 *Capsules buffered penicillin with pectin hydrolysate*—(a) *Potency.* Proceed as directed in § 141.1 except paragraph (i) thereof and in lieu of the directions in paragraph (d) of § 141.1 prepare samples as follows:

Place the contents of 12 capsules and the empty capsules into a 500 ml. volumetric flask. Add approximately 200 ml. of 1% phosphate buffer at pH 6.0, shake until the powder has dissolved and the capsules have gelatinized and make to 500 ml. with the phosphate buffer. Make the proper estimated dilutions in 1% phosphate buffer at pH 6.0. The average potency of capsules buffered penicillin with pectin hydrolysate is satisfactory if it contains not less than 85% of the number of units per capsule it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141.5 (a) utilizing the contents of 4 capsules.

§ 141.101 *Streptomycin sulphate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; potency.*—(a) *Cylinders (cups).* Use cylinders described under § 141.1 (a).

(b) *Culture media.* Using ingredients that conform to the standards prescribed by the U. S. P. or N. F., make nutrient agar for the seed and base layers:

Peptone	5.0 gm.
Beef extract	3.0 gm.
Agar	15.0 gm.
Distilled wate q. s.	1,000.0 ml.

pH 7.8 to 8.0 after sterilization.

(c) *Working standard.* Keep the working standard (obtained from the Food and Drug Administration) constantly in the refrigerator at 15° C. (59° F.) or below in tightly stoppered vials, which in turn are kept in larger stoppered tubes containing anhydrous calcium sulphate. Weigh out carefully in an atmosphere of 50 percent relative humidity or less appropriate amounts of the working standard and dilute in 0.05 M potassium phosphate buffer (pH 6.0). Keep this stock solution at a temperature of about 15° C.; do not use it later than 30 days after it is made.

(d) *Standard curve.* Prepare daily in 0.10 M potassium phosphate buffer (pH 7.8 to 8.0) a 20 mcg./ml. solution from the stock solution described in § 141.101 (c). Transfer to ten 100 ml. volumetric flasks, containing the same buffer, the required quantities of this 20 mcg./ml. solution to give 0.6, 0.7, 0.8, 0.9, 1.0, 1.1, 1.2, 1.3, 1.4 and 1.5 mcg./ml. solutions. A total of 27 plates is used in the preparation of the standard curve, three plates for each solution except the 1.0 mcg./ml. solution. The latter concentration is used as the reference point and is included on each plate. On each of three plates fill 3 cylinders with the 1.0 mcg./ml. standard and the other 3 cylinders with the concentration under test. Thus there will be 81 one microgram determinations and 9 determinations for each of the other points on the curve. After the plates have incubated read the diameters of the circles of inhibition. Average the readings of the 1.0 mcg./ml. concentration and the readings of the point tested for each set of 3 plates and average also all 81 readings of the 1.0 mcg./ml. concentration. The average of the 81 readings of the 1.0 mcg./ml. concentration is the correction point for the curve. Correct the average value obtained for each point to the figure it would be if the 1.0 mcg./ml. reading for that set of three plates were the same as the correction point. Thus, if in correcting the 0.8

unit concentration, the average of the 81 readings of the 1.0 mcg./ml. concentration is 16.5 mm. and the average of the 1.0 mcg./ml. concentration of this set of 3 plates is 16.3 mm. the correction is 0.2 mm. If the average reading of the 0.8 mcg./ml. concentration of these same 3 plates is 15.9 mm. the corrected value is then 16.1 mm. Plot these corrected values including the average of the 1.0 mcg./ml. concentration on 2 cycle semi-log paper using the concentration in mcg./ml. as the ordinate (the logarithmic scale) and the diameter of the zone of inhibition as the abscissa. Draw the standard curve through these points. The ten points selected to determine the curve are arbitrary and should be so chosen that the limits of the curve will fill the needs of the laboratory. However, the potency of the sample under test should fall in the interval of from 60% to 150% of the correction point of the standard curve.

(e) *Preparation of sample.* Dissolve volumetrically in sterile, distilled water, the sample to be tested to make a convenient stock solution. Further dilute this solution volumetrically to contain 100 mcg. of streptomycin base (estimated) per ml. Transfer 1.0 ml. of this 100 mcg. (estimated) per ml. solution to a 100 ml. flask and make up to volume with 0.10 M potassium phosphate buffer (pH 7.8 to 8.0). Use this last dilution in the assay for potency.

(f) *Preparation of spore suspension.* The test organism is Bacillus subtilis (American Type Culture Collection 6633). Maintain the test organism on nutrient agar prepared as described in § 141.1 (b) (1). Prepare a spore suspension by growing the organism in Roux bottles on agar of this same composition for one week at 37° C. Suspend the spores in sterile distilled water and heat for 30 minutes at 65° C. Wash the spore suspension three times with sterile distilled water, heat again for 30 minutes at 65° C. and resuspend in sterile distilled water. Maintain the spore suspension at approximately 15° C. Determine by appropriate tests the quantity of spore suspension to be added to each 100 ml. of agar for the secondary layer that will give sharp clear zones of inhibition.

(g) *Preparation of plates.* Add 21 ml. of agar described in paragraph (b) of this section to each Petri dish (20×100 mm.). Melt the agar to be used for the secondary layer, cool to 55 to 60° C. and add the spore suspension prepared in § 141.101 (f). Mix thoroughly and add 4 ml. to each of the plates containing the 21 ml. of the uninoculated agar. Tilt the plates back and forth to spread the inoculated agar evenly over the surface. Refrigerate until ready to add streptomycin (at least 1 hour).

(h) *Plate assay.* Place six cylinders on the inoculated agar surface so that they are at approximately 60° intervals on 2.8 cm. radius. Use three plates for each sample. Fill three cylinders on each plate with the 1.0 mcg./ml. standard and three cylinders with the 1.0 mcg./ml. (estimated) sample, alternating standard and sample. Incubate the plates for 16 to 18 hours at 37° C. and measure the diameter of each circle of inhibition.

(i) *Estimation of potency.* Average the zone readings of the standard and average the zone readings of the sample on the three plates used. If the sample gives a larger average zone size than the average of the standard, add the difference between them to the 1.0 mcg. zone size of the standard curve. If the average sample value is lower than the standard value, subtract the difference between them from the 1.0 mcg. value on the curve. From the curve read the potencies corresponding to these corrected values of zone sizes.

(j) *Turbidimetric assay.* (1) Employ the agar described in paragraph (b) of this section (adjusted to a final pH 7.0) for maintaining the test organism, which is Klebsiella pneumoniae (P. C. I. 602) non-capsulated. Transfer stock cultures every two weeks for test purposes. Transfer the organism to fresh agar slants and incubate at 37° C. for 6 hours. Suspend the growth from two or three of these slants in sterile distilled water and add approximately 5 ml. of culture suspension to each of two Roux bottles containing the agar described in paragraph (b) of this section. Incubate the bottles for six hours at 37° C., harvest the growth and suspend in sufficient sterile distilled water to give a light transmission reading of 80% using a filter at 6500 Ångstrom units in a photoelectric colorimeter. Keep the resulting suspension of organisms in the refrigerator and use for a period not to exceed two weeks. Prepare a daily inoculum by adding 6.0 ml. of this suspension to each 100 ml. of the nutrient broth prepared as directed in paragraph (b) (3) of this section cooled to a temperature of approximately 15° C.

(2) *Working standard solutions.* Add the following amounts of a 1000 microgram per ml. solution prepared from the stock solution described in paragraph (c) of this section to 100 ml. volumetric flasks containing sterile distilled water and bring to volume to give the working stock solutions tabulated below. These 9 flasks are well stoppered and maintained at approximately 15° C. for one month. Prepare final dilutions daily by adding 2.1 ml. of each of these 9 working stock solutions to 4.8 ml. of sterile distilled water. Add 1.0 ml. of each final dilution to each of six 14 x 124 mm. tubes (total 54 tubes). Add 9.0 ml. of inoculated broth described in subparagraph (1) of this paragraph to each tube and place immediately in a 37° C. water bath for 4 hours. The final concentration of streptomycin per ml. of broth is also included in the table below.

Amount of standard solution (1,000 mcg./ml.)	Working conc./ml. (also per cent conc.)	Final conc. (mcg./ml.) after addition of distilled water and broth
Ml.	*Mcg.*	*Mcg.*
6.0	60	1.8
7.0	70	2.1
8.0	80	2.4
9.0	90	2.7
10.0	100	3.0
11.0	110	3.3
12.0	120	3.6
13.0	130	3.9
14.0	140	4.2

(3) *Preparation of sample.* Dilute the sample under test with sterile distilled water to contain 100 mcg./ml. (estimated). To 2.1 ml. of the sample add 4.8 ml. sterile distilled water. Add 1.0 ml. of this dilution to each of six 14 x 124 mm. tubes. Add 9.0 ml. of the inoculated broth described in subparagraph (1) of this paragraph to each tube and place immediately in a 37° C. water bath for 4 hours. A control tube containing 1.0 ml. of distilled water and 9.0 ml. of the inoculated broth is similarly incubated. After incubation, add 4 drops of formalin to each tube, and read the light transmission in a photoelectric colorimeter, using a broad band filter having a wave length of 5,300 Ångstrom units.

(4) *Estimation of potency.* Average the light transmission readings for each concentration of the standard. Plot these values on cross section paper, employing average light transmission readings as the ordinate, and streptomycin concentration per ml. of broth as the abscissa. Prepare the standard curve by connecting successive points with a straight edge. Since the final concentration of streptomycin per ml. of broth is equivalent to the concentration per ml. of the working stock solution (see table in subparagraph (2) of this paragraph) the latter concentrations for each concentration level of the standard may be expressed as percent and substituted on the abscissa of the standard curve. If this is done the percent potency of the sample under test may be read directly from the standard curve.

(k) The potency of streptomycin salts is satisfactory, when assayed by the methods described in this section, if the immediate containers are represented to contain the equivalent of 200 milligrams or less of streptomycin base and contain 85% or more of the number of milligrams so represented; more than the equivalent of 200 milligrams of streptomycin base and contain 90% or more of the number of milligrams so represented.

§ 141.102 *Streptomycin sulphate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; sterility—* (a) *Culture medium.* Prepare fluid thioglycollate medium as described in § 141.2 (a).

(b) *Conduct of test.* Add aseptically 20 ml. of sterile distilled water to the sample under test. (This will give a concentration of approximately 50 mg. of streptomycin per ml. with the 1 gm. vial.) Transfer the equivalent of 25 mg. of this solution to 5 ml. of a sterile solution of 1:300 hydroxylamine hydrochloride adjusted to pH 6.0 with sodium hydroxide. The hydroxylamine hydrochloride is sterilized at 15 lbs. pressure (121° C.) for 20 minutes and prepared once a week. Mix thoroughly and let stand for one hour. Transfer 1.0 ml. of the inactivated streptomycin to each of four tubes containing 15 ml. of fluid thioglycollate medium. Inoculate one of these tubes with 1.0 ml. of a 1:1000 dilution of a 3 to 4 hour broth (§ 141.101 (j) (1)) culture of Klebsiella pneumoniae (P. C. I. 602) and incubate all four tubes for four days at 37° C. The inoculated tube should show growth at the end of four days; if so

and no other tube shows growth, the sample is sterile.

§ 141.103 *Streptomycin sulphate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; toxicity.* Proceed as directed in § 141.4 using as a test dose 0.5 ml. of a solution containing 2 mg./ml.

§ 141.104 *Streptomycin sulphate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; pyrogens.* Proceed as directed in § 141.3 using as a test dose 1.0 ml. per kg. of a solution containing 10 mg./ml.

§ 141.105 *Streptomycin sulphate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; histamine.* Use a healthy adult cat as the test animal. Determine weight and place under general anesthesia by employing sufficient (150 mg./kg.) sodium phenobarbital administered intraperitoneally. Surgically expose the right carotid separating it completely from all surrounding structures, including the vagus nerve, by blunt dissection and cannulate. Surgically expose the femoral vein. Start the recording kymograph and inspect the tracings for amplitude of excursion and relative stability of pressure. Determine the sensitivity of the animal by injecting into the femoral vein standard solutions of histamine made to contain the equivalent of 1.0 mcg. of histamine base per ml. Make injections at not less than 5-minute intervals using doses of 0.05, 0.1, and 0.15 mcg. of histamine base per kg. Repeat these injections, disregarding the first series of readings, until the drop given by equivalent doses of histamine is relatively uniform. The fall in blood pressure given by 0.1 mcb./kg. of histamine base (not less than 20 mm. of mercury) is subsequently employed as the standard in testing samples. The histamine standard is supplied on request. Inject 3 mg./kg. of the sample of streptomycin which has been diluted in saline to contain 3.0 mg. (estimated) of streptomycin per ml. maintaining the five-minute injection schedule. If a significant drop is encountered the dose is repeated after the animal has been retested with the standard histamine. If the animal remains reasonably stable, six to eight samples may be examined. The product is satisfactory if the fall in blood pressure obtained with 3 mg. of streptomycin per kg. of body weight is no greater than the fall obtained with 0.1 mcg. of histamine base per kg. of body weight. (Dogs may be substituted for cats in this test provided the ratio of the doses of streptomycin and histamine employed is the same.)

§ 141.106 *Streptomycin sulphate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride*—(a) *Moisture.* Proceed as directed in § 141.5 (a).

(b) *pH.* Proceed as directed in § 141.5 (b) using a solution with a concentration of 0.2 gm./ml.

(c) *Clarity.* Proceed as directed in § 141.5 (c) using an aqueous solution with a concentration of 0.2 gm./ml.

This order, which provides for tests and methods of assay of a new penicillin product, capsules buffered penicillin with pectin hydrolysate, and which includes a revision of all of the existing regulations for tests and methods of assay of penicillin-containing drugs heretofore promulgated and published in Part 141 and which also provides for tests and methods of assay of streptomycin-containing drugs, shall become effective upon publication in the FEDERAL REGISTER since both the public and the affected industries will benefit by the earliest effective date, and I so find.

Notice and public procedure are not necessary prerequisites to the promulgation of this order and would be contrary to the public interest, and I so find, since it was drawn in collaboration with interested members of the affected industries and since it would be against public interest to delay the marketing of these drugs products.

Dated: April 1, 1947.

[SEAL] WATSON B. MILLER,
Administrator.

[F. R. Doc. 47-3238; Filed, Apr. 3, 1947; 8:47 a. m.]

PART 144—CERTIFICATION OF BATCHES OF DRUGS COMPOSED WHOLLY OR PARTLY OF INSULIN

By virtue of the authority vested in the Federal Security Administrator by provisions of section 506 of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040, 1055, as amended by 55 Stat. 851; 21 U. S. C., Sup. V, 356), the regulations for the certification of batches of drugs composed wholly or partly of insulin, as amended, are hereby repealed, and the following regulations substituted therefor:

Sec.
144.1 Definitions and interpretations of terms.
144.2 Requests for certification; samples; storage; approvals preliminary to certification.
144.3 Certifications.
144.4 Conditions on the effectiveness of certificates.
144.5 Packaging.
144.6 Labeling.
144.7 Distinguishing colors on packages.
144.8 Records of distribution.
144.9 Authority to refuse certification service.
144.10 Fees.
144.11 Standards of quality, and purity for protamine.
144.12 Standards of identity, strength, quality and purity for globin insulin (with zinc).
144.13 Tests and methods of assay.

AUTHORITY: §§ 144.1 to 144.13, inclusive, issued under sec. 506, 55 Stat. 851; 21 U. S. C. Sup. 356.

§ 144.1 *Definitions and interpretations of terms.* For the purpose of the regulations in this part:

(a) The term "insulin" means the active principle of pancreas which affects the metabolism of carbohydrate in the animal body and which is of value in the treatment of diabetes mellitus.

(b) The term "insulin U. S. P." means the insulin injection recognized in the official United States Pharmacopoeia, including supplements thereto.

(c) The term "protamine zinc insulin" means the protamine zinc insulin injection recognized in the official United States Pharmacopoeia, including supplements thereto.

(d) The term "globin insulin (with zinc)" means the insulin preparation described in § 144.12.

(e) The term "master lot" means a quantity, which is purified and which has been mixed in one container so as to be homogeneous, of (1) a concentrated solution of insulin, or (2) the insulin-containing solids, in amorphous or crystalline form, derived from one or more such solutions.

(f) The term "batch" means a quantity of a drug, in labeled packages, of uniform composition and intended for administration without further change, in which the sole insulin-containing ingredient is a single dilution (which has been mixed in one container so as to be homogeneous) of (1) a single master lot or part thereof, or (2) a mixture of two or more master lots or parts thereof; except that such term means a portion of such quantity when certification of such portion is requested.

(g) The term "master lot mark" means an identifying mark or other identifying device assigned to a master lot by the manufacturer thereof.

(h) The term "batch mark" means an identifying mark or other identifying device assigned to a batch by the manufacturer thereof.

(i) The term "Commissioner" means the Commissioner of Food and Drugs.

(j) The functions and duties of the Commissioner under the regulations in this part may be exercised by such other responsible officials of the Food and Drug Administration as the Commissioner may designate for that purpose.

(k) The definitions and interpretations of terms contained in section 201 of the act shall be applicable to such terms when used in the regulations in this part.

§ 144.2 *Requests for certification; samples; storage; approvals preliminary to certification.* (a) A request for certification of a batch shall be addressed to the Commissioner, Food and Drug Administration, Federal Security Agency, Washington 25, D. C. A request from a foreign manufacturer shall be signed by such manufacturer and by an agent of such manufacturer who resides in the United States.

(b) The initial request for certification submitted by any person shall be preceded or accompanied by a full statement of the facilities and controls used to maintain the identity, strength, quality, and purity of each batch, including a description of (1) the equipment, methods, and processes used in diluting master lots and parts thereof, and in maintaining the identity, strength, quality, and purity of master lots and dilutions

therefrom; (2) the tests and assays made on master lots and mixtures thereof, on dilutions and batches therefrom, and on ingredients used in such dilutions and batches; and (3) the laboratory facilities used in such controls. Such initial request shall also be preceded or accompanied by the keys to the master lot marks and batch marks used by such person. When any change is made in any of such facilities or controls, or in any such key, the next request for certification thereafter shall be accompanied by a full statement of such change.

(c) A person who requests certification of a batch shall submit in connection with his request statements showing:

(1) The master lot mark of each master lot used or to be used wholly or partly as an ingredient or component of an ingredient of the batch;

(2) The quantity of each such master lot so used;

(3) The original quantity of each such master lot (unless such information has been previously submitted);

(4) The quantity of the batch; and

(5) The batch mark.

(d) Except as otherwise provided in paragraphs (g) and (h) of this section, a person who requests certification of a batch shall submit in connection with his request and in the quantities hereinafter indicated, accurately representative samples of the following:

(1) The single master lot or the mixture of two or more master lots or parts thereof, to be used as an ingredient of the batch; in a quantity containing approximately 10,000 U. S. P. Units of insulin.

(2) A trial dilution made from such master lot or mixture, glycerine, phenol or cresol, and hydrochloric acid, which dilution conforms to the standard of identity, strength, quality, and purity for insulin U. S. P., except that it may contain either 20 U. S. P. Units or 40 U. S. P. Units of insulin per cubic centimeter; in a quantity containing approximately 2,500 U. S. P. Units of insulin.

(3) If the batch is to be protamine zinc insulin, a trial mixture which is intended to be accurately representative of the mixture which will constitute the finished batch; in a quantity containing approximately 2,500 U. S. P. Units of insulin.

(4) If the batch is to be protamine zinc insulin, the lot of protamine used as an ingredient of the trial mixture referred to in subparagraph (3) of this paragraph; in a quantity of approximately 2 grams.

(5) If the batch is to be globin insulin (with zinc), a trial mixture made from the master lot or mixture referred to in subparagraph (1) of this paragraph, globin, zinc chloride, hydrochloric acid, glycerin, and phenol or cresol, which mixture is intended to be accurately representative of the mixture which will constitute the finished batch; in a quantity containing approximately 2,500 U. S. P. Units of insulin.

(6) If the batch is to be globin insulin (with zinc), the lot of globin hydrochloride from which the globin is to be prepared for use as an ingredient of the trial mixture referred to in subparagraph (5) of this paragraph; in a quantity of approximately 5 grams.

(7) The finished batch; in a quantity not less than 5 packages.

(e) Except as otherwise provided by paragraphs (g) and (h) of this section, a person who requests certification shall submit in connection with his request results of the tests and assays listed after each of the following materials, made by him on a sample of such material:

(1) The master lot or mixture, referred to in paragraph (d) (1) of this section: Ash, nitrogen, potency, reaction, sterility, and zinc, if such master lot or mixture is a solution; ash, moisture, nitrogen, potency, and zinc, if such master lot or mixture is a solid.

(2) A trial dilution from such master lot or mixture, of the potency of the trial dilution referred to in paragraph (d) (2) of this section: Ash, nitrogen, reaction, potency, and zinc.

(3) If the batch is to be protamine zinc insulin, the trial mixture referred to in paragraph (d) (3) of this section: Nitrogen, reaction, zinc, and biological reactions (by the tests prescribed in the official United States Pharmacopoeia, including supplements thereto).

(4) If the batch is to be protamine zinc insulin, the protamine referred to in paragraph (d) (4) of this section: Moisture, nitrogen, and sulfate.

(5) If the batch is to be globin insulin (with zinc), the trial mixture referred to in paragraph (d) (5) of this section: Nitrogen, reaction, zinc, and biological reaction (by the test prescribed in § 144.13 (b) or (c)).

(6) If the batch is to be globin insulin (with zinc), the globin hydrochloride referred to in paragraph (d) (6) of this section: Moisture, nitrogen, chloride, and ash.

(7) The finished batch: Nitrogen, reaction, sterility, zinc, and if the batch is insulin U. S. P., ash.

(f) The results of tests and assays for the following shall be reported in the terms indicated:

(1) Ash (except globin hydrochloride)—milligrams per 1,000 U. S. P. Units of insulin.

(2) Ash in globin hydrochloride—percent by weight.

(3) Chloride—percent by weight as HCl.

(4) Moisture—percent by weight.

(5) Nitrogen (except in globin hydrochloride and protamine)—milligrams per cubic centimeter in the cases of solutions and suspensions, and percent by weight in the case of solids.

(6) Nitrogen in globin hydrochloride—percent by weight calculated to a moisture-free, ash-free, chloride-free basis.

(7) Nitrogen in protamine—percent by weight, calculated to a moisture-free basis.

(8) Potency—U. S. P. Units of insulin per cubic centimeter in the case of solutions, and U. S. P. Units of insulin per milligram in the case of solids.

(9) Reaction—hydrogen ion concentration (pH).

(10) Sulfate—percent by weight, as SO_4, calculated to a moisture-free basis.

(11) Zinc—milligrams per cubic centimeter in the cases of solutions and suspensions, and percent by weight in the case of solids.

(g) (1) No sample referred to in paragraphs (d) (1) to (6) of this section, inclusive, and no result referred to in paragraphs (e) (1) to (6) of this section, inclusive, is required if such sample or result has been submitted in connection with a previous request for certification. No sample referred to in paragraph (d) (3) of this section and no result referred to in paragraph (e) (3) of this section is required if the batch is to be protamine zinc insulin of 80-unit strength, and the Commissioner has previously approved a trial mixture referred to in paragraph (d) (3) of this section of 40-unit strength, prepared from the same materials and in the same manner (except for adjustment of reaction of the buffer solution) as such batch of 80-unit strength is to be made. No sample, referred to in paragraph (d) (5) of this section and no result referred to in paragraph (e) (5) of this section is required if the batch is to be globin insulin (with zinc) of 80-unit strength, and the Commissioner has previously approved a trial mixture referred to in paragraph (d) (5) of this section of 40-unit strength, prepared from the same materials and in the same manner as such batch of 80-unit strength is to be made.

(2) Each sample submitted pursuant to this section shall be so packaged as to maintain its representative character, and in the case of any solution or suspension, shall be collected and packaged under aseptic conditions. Each package shall be clearly identified as to its contents and shall bear the name and post-office address of the person submitting the request.

(3) The packages constituting the samples submitted pursuant to paragraph (d) (7) of this section shall be collected at such intervals that the quantities packaged between collections are approximately equal; in no case shall any such quantity be more than 10,000 packages. The collections shall cover the entire period of packaging.

(4) Each sample submitted pursuant to paragraphs (d) (2), (3), and (5) of this section shall be accompanied by a statement showing the identity, quality, and quantity of each substance used as an ingredient or as a component of an ingredient in the material from which the sample was taken.

(5) If the tests and assays, results of which are submitted pursuant to paragraph (e) (2) of this section, were not made on the same trial dilution as that from which the sample submitted pursuant to paragraph (d) (2) of this section was taken, such sample shall be accompanied by a statement showing the identity, quality, and quantity of each substance used as an ingredient or as a component of an ingredient of the trial dilution on which such tests and assays were made.

(6) The value for each of the components ash, nitrogen, and zinc submitted pursuant to paragraphs (e) (1) and (2) of this section may be calculated from the result of a test therefor submitted

pursuant to either paragraph (e) (1) or (2) of this section. The result on potency required under paragraph (e) (1) of this section may be calculated from the result of an assay therefor submitted pursuant to paragraph (e) (2) of this section. The value of each of the components nitrogen and zinc, to the extent required under paragraph (e) (7) of this section, may be calculated from the result of a test therefor submitted pursuant to either paragraph (e) (3) or (5) of this section or from the result of a test of the bulk dilution from which the batch was prepared. The value for each of the components ash, nitrogen, and zinc required under paragraph (e) (7) of this section may, if the batch is insulin U. S. P., be calculated from the result of a test therefor submitted pursuant to paragraphs (e) (1) or (2) of this section or from the result of a test of the bulk dilution from which the batch was prepared. Each calculated value shall be indicated as such.

(7) The information required under paragraphs (c) (1), (2), and (3) of this section, and the samples and results of tests and assays required under paragraphs (d) (1) and (2) and (e) (1) and (2) of this section should be submitted before submission of the samples and results required in paragraphs (d) (3) to (6) of this section, inclusive, and (e) (3) to (6) of this section, inclusive; and the samples and results required under paragraph (d) (3) to (6), inclusive, and (e) (3) to (6), inclusive, should be submitted before submission of the information, samples, and results required under paragraphs (c) (4) and (5), (d) (7), and (e) (7) of this section. All information, including results of tests and assays (except results of tests for sterility), required under this section should be submitted at the same time as the samples to which they relate are submitted.

(h) The person who requests certifications shall submit such information additional to that submitted pursuant to paragraphs (b), (c), (e), and (g) of this section, such additional samples of any substance referred to in paragraph (d) of this section, and such samples of any other substance used or to be used as an ingredient or as a component of an ingredient in the batch, as the Commissioner may require for the purpose of investigations to determine whether or not such batch complies with the requirements set forth by § 144.2 for the issuance of a certificate.

(i) After a sample required by paragraph (d) of this section is taken from any master lot or mixture of parts of two or more master lots, such master lot or master lots and all parts thereof, and all dilutions and batches and all parts thereof in which any such master lot is used as an ingredient or as a component of an ingredient, shall be stored at the establishment where manufactured until used up or shipped or otherwise delivered, at a temperature above freezing but not above 15° C. (59° F.), and under such other conditions as prevent, so far as practicable, any change in composition; except that master lots and parts thereof which are solids may be stored at ordinary room temperatures.

(j) As promptly as practicable after the samples submitted pursuant to paragraphs (d) (1) and (2) of this section, and any other material or information relative thereto that may be required under this section, are received by the Commissioner, he shall notify the person who submitted such samples of his approval or refusal to approve the use of the master lot or mixture for the making of bulk dilutions. In case of a refusal to approve, the Commissioner shall state his reasons therefor.

(k) In like manner, the Commissioner shall notify the person who submits samples pursuant to paragraph (d) (3) to (6) of this section, inclusive, of his approval or refusal to approve the use of the materials represented by such samples in completing the manufacture of the batch. In case of a refusal to approve, the Commissioner shall state his reasons therefor.

(l) If, under the provisions of paragraphs (j) or (k) of this section, the Commissioner has refused to approve any material for use in a subsequent operation, he shall examine no other sample required hereunder which includes such material as an ingredient or component of an ingredient, unless and until the person requesting certification makes an adequate showing that the cause for such refusal no longer exists.

§ 144.3 *Certifications.* (a) If it appears to the Commissioner, after such investigation as he considers necessary, that:

(1) The information, including results of tests and assays, and the samples, required by or pursuant to § 144.2 have been submitted and such information contains no untrue statement of a material fact;

(2) The batch complies with these regulations and conforms to the standards of identity, strength, quality, and purity for insulin U. S. P., protamine zinc insulin, or globin insulin (with zinc); the Commissioner shall certify that such batch is safe and efficacious for use, subject to such conditions on the effectiveness of such certifications as are set forth in § 144.4, and shall issue to the person who requested it a certificate to that effect.

(b) If the Commissioner determines, after such investigation as he considers to be necessary, that the information submitted pursuant to § 144.2, or the batch covered by such request, does not comply with the requirements set forth in paragraph (a) of this section for the issuance of a certificate, the Commissioner shall refuse to certify such batch and shall give notice thereof to the person who requested certification, stating his reasons for refusal.

(c) For the purposes of his investigations under the authority of this section, the Commissioner may accept, when he is satisfied as to the completeness and accuracy thereof the results of any tests or assays made by the control laboratory of the Insulin Committee of the University of Toronto, pursuant to a licensing agreement entered into prior to the date of enactment of Public Law 366, 77th Cong., 1st Sess. (55 Stat. 851, 21 U. S. C. Sup. V, 356).

§ 144.4 *Conditions on the effectiveness of certificates.* (a) A certificate shall not become effective:

(1) If it is obtained through fraud, or through misrepresentation or concealment of a material fact;

(2) With respect to any package unless its immediate container complies with the requirements of § 144.5 and such package has been so sealed that its contents cannot be used without destroying such package or seal; or

(3) With respect to any package unless its label and labeling bear all words, statements, and other information, and are distinguished by the color or colors, required by §§ 144.6 and 144.7.

(b) A certificate shall cease to be effective:

(1) With respect to any package of insulin U. S. P., 2 years after such package is removed from the storage required by § 144.2 (i);

(2) With respect to any package of protamine zinc insulin, 18 months after the immediate container therein was filled, but in no case shall a certificate remain effective with respect to any package more than 12 months after it is removed from the storage required by § 144.2 (i);

(3) With respect to any package of globin insulin (with zinc), 18 months after the immediate container therein was filled, but in no case shall a certificate remain effective with respect to any package more than 12 months after it is removed from the storage required by § 144.2 (i);

(4) With respect to any package, when such package or the seal thereof or the immediate container therein is broken, or when its label or labeling ceases to conform to any requirement of § 144.6 or 144.7; or

(5) With respect to any package when the drug therein so changes that it fails to meet the standards of identity, strength, quality, and purity upon the basis of which the batch was certified; except that those minor changes in potency (not exceeding 10 percent from the potency stated on the label, in the case of insulin U. S. P.) which occur before the expiration date, and which are normal and unavoidable in good storage and distribution practice, shall be disregarded.

§ 144.5 *Packaging.* Each batch shall be packaged in immediate containers of colorless transparent glass. Such containers shall be closed with a substance through which successive doses may be withdrawn by hypodermic needle without removing the closure or destroying its effectiveness. The containers and closures shall be sterile at the time the containers are filled and closed. The composition of the containers and closures shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor prescribed in applicable standards of strength, quality, and purity.

§ 144.6 *Labeling.* Each package from a batch that has been certified in accordance with the regulations in this part shall bear, on its label or labeling as hereinafter indicated, the following:

(a) On the outside wrapper or container and the immediate container of the retail package:

(1) The batch mark of such batch; and

(2) The strength of the drug in terms of U. S. P. Units of insulin per cubic centimeter.

(b) On the outside container or wrapper of the retail package:

(1) The statement "Expiration date ____", the blank being filled in with the date on which the certificate applicable to such batch expires with respect to such package, as provided in § 144.4 (b) (1), (2), or (3); and

(2) The statement "Keep in a cold place; avoid freezing".

(c) On the circular or other labeling of the retail package:

(1) A statement that the treatment of diabetes mellitus is an individual problem and that the use of the drug, the time of its administration, the number of daily doses and the quantity of each, as well as diet and exercise, are problems which require direct and continuous medical supervision;

(2) A statement explaining that the volume of the dose depends on the number of units of insulin per cubic centimeter stated on the label, and that the patient should understand the meaning of the volume markings on the syringe;

(3) A description of a practicable method for sterilizing the needle and syringe before use;

(4) A description of the technique of withdrawal from the vial and the use of an antiseptic on the stopper, and a caution against the removal of the stopper;

(5) A description of the technique for cleansing, and the use of an antiseptic on, the site of injection;

(6) A statement that failure to comply with the techniques described in subparagraphs (3), (4), and (5) of this paragraph may lead to infection of the patient;

(7) A statement that injection should be subcutaneous, at a different site from that of the preceding injection, and a caution against intravenous or intramuscular use;

(8) An explanation of hypoglycemia and its relation to over-dosage, omission of meals, illness, and infection;

(9) A statement of the significance of sugar in the urine and of the necessity of tests therefor; and

(10) A caution against use after the expiration date shown on the outside wrapper or container.

(d) On the circular or other labeling of the retail package, if the batch is insulin U. S. P. (in addition to the information required by paragraphs (a), (b), and (c) of this section), a caution against use if the drug has become viscous or if its color has become other than water clear.

(e) On the outside wrapper or container and the immediate container of the retail package, if the batch is protamine zinc insulin (in addition to the information required by paragraphs (a), (b), and (c) of this section), the statement "Shake carefully," or "Shake well before using," or "Shake well."

(f) On the circular or other labeling of the retail package, if the batch is protamine zinc insulin (in addition to the information required by paragraphs (a), (b), (c), and (e) of this section):

(1) An explanation of the difference, as compared with insulin U. S. P., in onset of action, duration, and the time and frequency of administration;

(2) A caution that it is not to be substituted for insulin U. S. P., except on the advice and direction of a physician;

(3) A statement that a uniform suspension of the preparation is necessary and is brought about by careful shaking before use;

(4) A caution against use when the precipitate has become lumped or granular in appearance or has formed a deposit of solid particles on the wall of the container.

(g) On the circular or other labeling of the retail package, if the batch is globin insulin (with zinc), (in addition to the information required by paragraphs (a), (b), and (c) of this section):

(1) An explanation of the difference, as compared with insulin U. S. P. and with protamine zinc insulin, in onset of action, duration, and the time and frequency of administration;

(2) A caution that it is not to be substituted for insulin U. S. P. or protamine zinc insulin, except on the advice and direction of the physician; and

(3) A caution against use if any turbidity or precipitate has developed in the solution.

§ 144.7 *Distinguishing colors on packages.* (a) The outside containers or wrappers of the packages, and the labels on the immediate containers, of each strength of insulin U. S. P. shall be distinguished by the following color:

Red, if it contains 40 U. S. P. Units of insulin per cubic centimeter;

Green, if it contains 80 U. S. P. Units of insulin per cubic centimeter;

Orange, if it contains 100 U. S. P. Units of insulin per cubic centimeter;

But if the master lot used was in crystalline form, the distinguishing colors, instead of those prescribed above, may be the following:

Red and gray, if it contains 40 U. S. P. Units of insulin per cubic centimeter;

Green and gray, if it contains 80 U. S. P. Units of insulin per cubic centimeter.

(b) The outside containers or wrappers of the packages, and the labels on the immediate containers, of each strength of protamine zinc insulin shall be distinguished by the following colors:

Red and white, if it contains 40 U. S. P. Units of insulin per cubic centimeter;

Green and white, if it contains 80 U. S. P. Units of insulin per cubic centimeter.

(c) The outside containers or wrappers of the packages, and the labels of the immediate containers, of each strength of globin insulin (with zinc) shall be distinguished by the following colors:

Red and brown, if it contains 40 U. S. P. Units of insulin per cubic centimeter;

Green and brown, if it contains 80 U. S. P. Units of insulin per cubic centimeter.

§ 144.8 *Records of distribution.* (a) The person to whom a certificate is issued shall keep complete records showing each shipment and other delivery (including exports) of each batch or part thereof, by the person requesting certification, and showing each such shipment and delivery into, or from any place in, any state or territory, made by any person subject to his control, including records showing the date and quantity of each such shipment and delivery and the name and post office address of the person to whom such shipment or delivery was made.

(b) Upon the request of any officer or employee of the Food and Drug Administration or of any other officer or employee of the United States, acting on behalf of the Administrator, the person to whom a certificate is issued, at all reasonable hours within three years after disposal of all the batch covered by such certificate, shall make such records available to any such officer or employee, and shall accord to such officer or employee full opportunity to make inventory of stocks of such batch on hand and otherwise to check the correctness of such records.

§ 144.9 *Authority to refuse certification service.* When the Administrator finds, after giving notice and opportunity for hearing, that a person has:

(a) Obtained or attempted to obtain a certificate through fraud, or through misrepresentation or concealment of a material fact;

(b) Falsified the records required to be kept by § 144.8; or

(c) Failed to keep such records or to make them available, or to accord full opportunity to make an inventory of stocks on hand or otherwise to check the correctness of such records, as required by such section, the Administrator may immediately suspend service to such person under the regulations in this part and may continue such suspension unless and until such person shows adequate cause why such suspension should be terminated.

§ 144.10 *Fees.* (a) Fees for the services rendered under the regulations in this part shall be such as are necessary to provide, equip, and maintain an adequate certification service.

(b) The fees for the services rendered with respect to the samples submitted pursuant to § 144.2 (d) shall be:

(1) For each master lot or mixture of two or more master lots or parts thereof as follows:

(i) $50 if the master lot or mixture has not been previously approved by the Commissioner.

(ii) $25 if the master lot or mixture has been previously approved by the Commissioner in accordance with § 144.2 (j).

(2) For each trial dilution as follows:

(i) $50 if the results of an assay for potency of a trial dilution made by the laboratory referred to in § 144.3 (c) are submitted or are to be submitted.

(ii) The cost of the services rendered if the results referred to in subparagraph (2) (i) of this paragraph are not submitted and are not to be submitted.

(3) For each trial mixture of protamine zinc insulin as follows:

(i) $50 if the results of tests for biological reactions made by the laboratory referred to in § 144.3 (c) are submitted or are to be submitted.

(ii) The cost of the services rendered if the results referred to in subparagraph (3) (i) of this paragraph are not submitted and are not to be submitted.

(4) $50 for each lot of protamine.

(5) The cost of the services rendered for each trial mixture of globin insulin (with zinc).

(6) $50 for each lot of globin hydrochloride.

(7) $8.00 for each package in the sample of the finished batch.

Except as otherwise provided by paragraph (c) of this section, each request for certification submitted, or the initial sample or samples submitted in connection therewith pursuant to § 144.2 (d), which ever is sent first to the Commissioner, shall be accompanied by such fees as are prescribed in specific amounts for the samples submitted. When the fee is the cost of the services rendered, each sample referred to in subparagraph (2) (ii) of this paragraph shall be accompanied by an advance deposit of $1,200, each sample referred to in subparagraphs (3) (ii) and (5) of this paragraph shall be accompanied by an advance deposit of $500, and thereafter such additional advance deposits shall be made as the Commissioner estimates may be necessary to prevent arrears in the payment of such fee.

(c) A person requiring continuing certification services may maintain an advance deposit of the estimated costs of such services for a period of two months or more. Such deposits shall be debited with fees for services rendered, but shall not be debited for any fee the amount of which is not definitely specified in these regulations unless the depositor has previously requested the performance of the services to be covered by such fee. A monthly statement for each such advance deposit shall be rendered.

(d) The unearned portion of any advance deposit made pursuant to paragraph (b) or (c) of this section shall be refunded to the depositor upon his application.

(e) All advance deposits required by the regulations in this part shall be paid by money order, bank draft, or certified check drawn to the order of the Treasurer of the United States, collectible at par, at Washington, D. C.

(f) All earned fees shall be deposited in the Treasury of the United States to the credit of Miscellaneous Receipts, Federal Security Agency.

§ 144.11 *Standards of quality and purity for protamine.* When protamine is dried to constant weight at 100° C., its total nitrogen content is not less than 22.5 percent and not more than 25.5 percent, and its sulfate content, calculated as SO_4, is not less than 16 percent and not more than 19 percent.

§ 144.12 *Standards of identity, strength, quality, and purity for globin insulin (with zinc).* Globin insulin (with zinc) is a preparation, in a hydrochloric acid medium, of insulin modified by the addition of globin and zinc chloride. The quantity of insulin used is such that each cubic centimeter of the finished product contains either 40 or 80 U. S. P. Units of insulin. The quantity of globin used (calculated as 6.0 times its nitrogen content) is not less than 3.6 milligrams and not more than 4.0 milligrams for each 100 U. S. P. Units of insulin used. The preparation also contains, for each 100 U. S. P. Units of insulin used, not less than 0.25 milligram and not more than 0.35 milligram zinc and not more than 1.50 milligrams total nitrogen. The pH of the finished preparation is not less than 3.4 and not more than 3.8. If necessary, either hydrochloric acid or sodium hydroxide may be added to attain the required pH. The finished preparation also contains not less than 1.30 and not more than 1.70 percent (w/v) glycerin, and not less than 0.15 and not more than 0.20 percent (w/v) cresol U. S. P., or not less than 0.20 and not more than 0.26 percent (w/v) phenol U. S. P. The preparation is sterile. The globin used is obtained from globin hydrochloride prepared from beef blood. The ash content of the globin hydrochloride is not more than 0.3 percent; its nitrogen content, calculated to a moisture, ash, and hydrochloric acid free basis, is not less than 16.0 percent and not more than 17.5 percent.

§ 144.13 *Tests and methods of assay.* The following tests and methods of assay are prescribed for the purposes of the regulations in this part. (All reagents specified herein shall be of U. S. P. quality or better.)

(a) *Tests and methods of assay for insulin U. S. P. and for protamine zinc insulin.* The tests and methods of assay for insulin U. S. P. and for protamine zinc insulin shall be those set forth therefor in the official United States Pharmacopoeia, including supplements thereto.

(b) *Biological reaction for globin insulin (with zinc) containing 40 U. S. P. Units of insulin per cubic centimeter.* The rate, amount, and duration of effect in lowering the blood sugar of rabbits by globin insulin (with zinc) is determined by comparing the average blood sugar concentrations at various intervals during not less than a 9-hour observation period following the administration of globin insulin (with zinc) subcutaneously into rabbits, with the average blood sugar concentrations similarly obtained by administration of globin insulin (with zinc) reference material prepared as hereinafter set forth.

(1) *Globin insulin (with zinc) reference material.* Prepare the globin insulin (with zinc) reference material to contain 40 U. S. P. units of insulin per cubic centimeter from the following component solutions (or solutions of the same proportionate composition per cubic centimeter) by adding with gentle shaking, to a suitable volume of Solution 2, accurately measured at room temperature, an equal volume of Solution 3. Test the reaction and if it is not within the limits of pH 3.4 to pH 3.8 discard and prepare a new mixture using a freshly prepared sample of Solution 3 in which the hydrogen ion concentration has been suitably adjusted. Store in a refrigerator and do not use after 6 months have elapsed from the date of preparation.

The solutions referred to above are:

Solution 1. Dissolve 0.299 gram zinc oxide in not less than 115 cubic centimeters and not more than 118 cubic centimeters of tenth-normal hydrochloric acid. Add 30 grams glycerin, 3.5 grams cresol (or 4.6 grams phenol) and sufficient distilled water to make the final volume 1,000 cubic centimeters.

Solution 2. Weigh accurately a suitable quantity of U. S. P. Zinc-Insulin Crystals Reference Standard and dissolve in such quantity of Solution 1 as to obtain a concentration of 80 U. S. P. Units of insulin per cubic centimeter. Store in a refrigerator; do not use after 3 months from the date of preparation.

Solution 3. Dissolve not less than 100 milligrams of the reference globin hydrochloride in distilled water in the proportion of 10 milligrams per cubic centimeter. To this solution add, dropwise, with gentle stirring, one-tenth of its volume of tenth-normal sodium hydroxide. Dilute with distilled water to make the final concentration equivalent to 3.36 milligrams of reference globin hydrochloride per cubic centimeter. This solution should be freshly prepared before use.

(2) *Test animal.* The test animal shall be the same as that described in the official United States Pharmacopoeia, including supplements thereto, for the assay of insulin U. S. P.

(3) *Volume of the globin insulin (with zinc) reference material to be injected.* The volume of the preparation to be injected shall be such that at a period of from 6 to 8 hours after the administration of the test material, the blood sugar is not greater than approximately 90 percent of the initial value but the volume is not so great as to cause convulsions in more than 25 percent of the animals. Do not dilute the preparations to be injected to attain the above requirements. Make injections with a micrometer syringe.

(4) *Conduct of the test and blood sugar determination.* Proceed as directed in the official United States Pharmacopoeia, including supplements thereto, for biological reaction for protamine zinc insulin, except that the samples of blood for determination of blood sugar concentrations are obtained over a period of not less than 9 hours, instead of 11 hours, after the injection.

(5) *Interpretation of data.* Subtract the average blood sugar concentration at each bleeding time for those rabbits injected with the preparation being tested from the average blood sugar concentration at the comparable bleeding time for those rabbits injected with the globin insulin (with zinc) reference material. The average blood-sugar concentrations at each bleeding time from the beginning

of the test up to and including 5 hours after the injection do not differ by more than 6 milligrams per 100 cubic centimeters and at each subsequent bleeding time do not differ by more than 8 milligrams per 100 cubic centimeters. Obtain the average of the differences for all bleeding times after the injection, taking into account the sign of each difference: the value obtained does not exceed the limits of plus or minus 5.

(c) *Biological reaction of globin insulin (with zinc) containing 80 U. S. P. Units of insulin per cubic centimeter.* Globin insulin (with zinc) containing 80 U. S. P. Units of insulin per cubic centimeter is tested according to the method prescribed in paragraph (b) of this section for the assay of globin insulin (with zinc) containing 40 U. S. P. Units of insulin per cubic centimeter except that the globin insulin (with zinc) reference material is so prepared as to contain 80 U. S. P. Units of insulin per cubic centimeter with zinc and globin in the same relative proportions per unit of insulin as specified for the globin insulin (with zinc) reference material in paragraph (b) of this section.

(d) *Identification of globin insulin (with zinc).* Adjust the acidity of globin insulin (with zinc) so that the pH is not less than 4.5 and not more than 5.5. A precipitate forms. Divide the sample containing the precipitate into two portions. Adjust the acidity of the first sample to a pH not less than 2.5 and not more than 3.5 and adjust the second sample to a reaction more alkaline than pH 11.0. In each case the precipitate dissolves giving a clear solution.

Inject subcutaneously into 6 rabbits, from which food has been withheld for the previous 18 to 24 hours and which weigh 1.8 to 2.2 kilograms each, a quantity of globin insulin (with zinc) which will cause convulsions in at least 3 animals. Immediately after convulsions occur in an animal, inject intravenously into that animal 5 cubic centimeters of a 50 percent aqueous solution of dextrose. The convulsion is relieved, and a majority of the animals which have shown convulsions remain alive for at least 3 days.

(e) *Sterility of globin insulin (with zinc).* Use the method described in the official United States Pharmacopoeia, including supplements thereto, for insulin U. S. P.

(f) *Chloride in globin hydrochloride*—(1) *Conduct of the test.* Weigh accurately approximately 0.5 gram of globin hydrochloride into a small beaker and dissolve in 10–15 cubic centimeters of distilled water. Add 10 cubic centimeters of tenth-normal silver nitrate, 5 cubic centimeters of nitric acid, and 5 cubic centimeters of a saturated solution of potassium permanganate. Stir and place on a steam bath for approximately one hour. If any brown color remains, stir again, rinse the sides of the beaker with distilled water and place on the steam bath until the brown color disappears. Transfer quantitatively to a 50-cubic centimeter volumetric flask and fill the flask to the mark with distilled water. Mix and filter through a dry filter paper into a dry vessel. Transfer exactly 40 cubic centimeters of the filtrate to a flask, add 2 cubic centimeters of ferric ammonium sulfate Test Solution and titrate with tenth-normal ammonium thiocyanate. To obtain the percent chloride as HCl, subtract 1.25 times the number of cubic centimeters of ammonium thiocyanate used from 10; multiply this difference by 0.365 and divide by the weight of the sample in grams.

(2) *Reagents.* The reagents used are those described in the official United States Pharmacopoeia, including supplements thereto.

(g) *Sulfate in protamine*—(1) *Conduct of test.* Weigh accurately about 10 milligrams of protamine into a small casserole or beaker, add 0.2 cubic centimeter of normal sodium hydroxide and evaporate carefully to dryness. Heat over a flame until a grayish-white ash results. Dissolve the ash in 1 cubic centimeter of tenth-normal hydrochloric acid, transfer quantitatively to a 50-cubic centimeter calibrated centrifuge tube, neutralize to litmus and make the volume to 10 cubic centimeters with distilled water.

To the neutral solution add 2 cubic centimeters of benzidine test solution, referred to in subparagraph (2) of this paragraph, and 4 cubic centimeters of 95 percent (w/v) solution of acetone in distilled water. Allow to stand for 10 minutes and centrifuge for not less than 15 minutes at approximately 3,000 revolutions per minute. Carefully remove the supernatant fluid by means of a pipette having a very small opening at the tip. Wash the precipitate twice, using 10 cubic centimeters of 95 percent acetone for each washing. Carefully remove the supernatant acetone and place the tube in a boiling water bath until the odor of acetone disappears. Suspend the precipitate with 10 cubic centimeters of distilled water, introduce 1 drop of phenolphthalein test solution U. S. P. and titrate while hot with fiftieth-normal sodium hydroxide to the first faint permanent pink, observing carefully whether all particles of the benzidine sulfate precipitate have dissolved and, if not reheating to bring the last traces into solution. Use a burette graduated in divisions of not more than 0.05 cubic centimeter so that readings can be estimated to 0.01 cubic centimeter.

Each cubic centimeter of fiftieth-normal sodium hydroxide is equivalent to 0.960 milligram of sulfate (SO_4). Calculate the results to a moisture-free basis.

(2) *Reagent.* Benzidine test solution. Dissolve 4 grams of benzidine in 45 cubic centimeters of normal hydrochloric acid and dilute to 250 cubic centimeters with distilled water. Before use, remove by filtration through ash-free filter paper any brown residue present.

(h) *Total nitrogen in globin insulin (with zinc) and globin hydrochloride.* Determine total nitrogen by the method described in the official United States Pharmacopoeia, including supplements thereto, for insulin U. S. P.

(i) *Zinc in insulin-containing solutions, in protamine zinc insulin, and in globin insulin (with zinc).* Use the method described in the official United States Pharmacopoeia, including supplements thereto, for insulin U. S. P.

(j) *Zinc in insulin-containing solids.* Dissolve 10 to 20 milligrams, accurately weighed, of insulin-containing solids in 5 to 10 cubic centimeters of distilled water containing 1 drop of five-normal hydrochloric acid, and proceed as directed in the official United States Pharmacopoeia, including supplements thereto, under the test for zinc in insulin U. S. P.

(k) The Commissioner shall, for the purposes of the tests and assays prescribed under this section, provide a suitable reference globin hydrochloride, and shall, at cost, furnish any person making written request therefor a sample thereof.

The foregoing order shall become effective on date of publication, since the public and the affected industry will benefit thereby, and I so find.

Notice and public procedure are not necessary prerequisites to the promulgation of this order, and I so find. The order is essentially a compilation of existing regulations heretofore promulgated and published in this part except that standards and tests and methods of assay for protamine zinc insulin, which appear in the latest official United States Pharmacopoeia and thus are unnecessary in these regulations, have been deleted. Some revision has been made in the reaction test for globin insulin (with zinc). These changes, as well as the original regulations and previous amendments, all of which appear in this compilation, were drawn in collaboration with the affected industry for whose convenience the compilation has been prepared.

Dated: March 31, 1947.

[SEAL] WATSON B. MILLER, *Administrator.*

[F. R. Doc. 47-3237; Filed, Apr. 3, 1947; 8:47 a. m.]

PART 146—CERTIFICATION OF BATCHES OF PENICILLIN OR STREPTOMYCIN-CONTAINING DRUGS

By virtue of the authority vested in the Federal Security Administrator by the provisions of sections 507 and 701 (a) of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040, 1055, as amended by 59 Stat. 463 and Pub. Law 16, 80th Cong., 1st Sess.; 21 U. S. C. 371 (a); 21 U. S. C. Sup. 357) the regulations for the certification of batches of penicillin-containing drugs (11 F. R. 12136), as amended, are hereby repealed and the following regulations for the certification of penicillin-containing drugs and streptomycin-containing drugs are substituted therefor:

DEFINITIONS

GENERAL PROVISIONS

Sec.

AUTHORITY: §§ 146.1 to 146.101, inclusive, issued under secs. 507, 701 (a), 52 Stat. 1040, as amended by 59 Stat. 463, Pub. Law 16, 80th Cong.; 21 U. S. C. and Sup., 357, 371 (a).

DEFINITIONS

§ 146.1 *Definitions and interpretations.* For the purpose of the regulations in this part:

(a) Each of the several antibiotic substances (e. g. penicillin F, penicillin G, penicillin X) produced by the growth of Penicillium notatum or Penicillium chrysogenum, and each of the same substances produced by any other means, is a kind of penicillin.

Whenever the term "penicillin" appears in the regulations in this part it means sodium penicillin, calcium penicillin, or potassium penicillin, or any combination of two or all of these, unless otherwise specified.

(b) Each of the several antibiotic substances produced by the growth of Streptomyces griseus and each of the same substances produced by any other means, is a kind of streptomycin.

Wherever the term 'streptomycin" appears in the regulations in this part it means streptomycin sulphate, streptomycin hydrochloride, streptomycin phosphate, or streptomycin trihydrochloride calcium chloride, or any combination of two or all of these, unless otherwise specified.

(c) The term "penicillin master standard" means a specific lot of crystalline sodium penicillin G (sodium penicillin II) which is designated by the Commissioner as the standard of comparison in determining the potency of the penicillin working standard.

(d) The term "streptomycin master standard" means a specific lot of crystalline trihydrochloride calcium chloride salt of streptomycin which is designated by the Commissioner as the standard of comparison in determining the potency of the streptomycin working standard.

(e) The term "unit" means a penicillin activity contained in 0.6 microgram of the penicillin master standard; the term "penicillin potency" means the number of such units in a specified quantity of a substance.

(f) The term "microgram" means the streptomycin activity (potency) contained in 1.3 micrograms of the streptomycin master standard.

(g) The term "penicillin working standard" means a specific lot of a homogeneous preparation of one or more penicillin salts; the term "streptomycin working standard" means a specific lot of a homogeneous preparation of one or more streptomycin salts; the potency of each preparation has been determined by comparison with its master standard and each has been designated by the Commissioner as working standards for use in determining the potency of drugs subject to the regulations in this part.

(h) The term "batch" means a specific homogeneous quantity of a drug.

(i) The term "batch mark" means an identifying mark or other identifying device asigned to a batch by the manufacturer or packer thereof.

(j) The term "Commissioner" means the Commissioner of Food and Drugs and any other officer of the Food and Drug Administration whom he may designate to act in his behalf for the purposes of the regulations in this part.

(k) The term "U. S. P." means the official Pharmacopoeia of the United States, including supplements thereto. The term "N. F." means the official National Formulary, including supplements thereto.

(l) The term "manufacture" does not include the use of a drug as an ingredient in compounding any prescription issued in his professional practice by a physician, dentist, or veterinarian licensed by law to administer or apply such drug.

(m) All statements, samples, and other information and materials submitted in connection with a request for certification shall be considered to be a part of such request.

(n) The definitions and interpretations of terms contained in section 201 of the act shall be applicable to such terms when used in the regulations in this part.

(o) Except as specifically provided by §§ 146.8 to 146.23, inclusive, no provision of any section in this part shall be construed as exempting any drug from any applicable provision of the act or other regulation thereunder.

(p) The regulation in Part 141 of this chapter prescribing tests and methods and methods of assays shall not be construed as preventing the Commissioner from using any other test or method of assay in his investigations to determine whether or not:

(1) A request for certification contains any untrue statement of a material fact; or

(2) A certificate has been obtained through fraud, or through misrepresentation or concealment of a material fact.

GENERAL PROVISIONS

§ 146.2 *Requests for working standards and certification; information and samples required.* (a) A request for certification of a batch shall be addressed to the Commissioner and shall be in a form specified by him. A request from a foreign manufacturer shall be signed by such manufacturer and by an agent of such manufacturer who resides in the United States.

(b) The initial request for certification of a batch of any drug submitted by any person shall be preceded or accompanied by a full statement of the facilities and controls used to maintain the identity, strength, quality, and purity of each batch, including a description of (1) the methods and processes used in the manufacture of the drug; (2) the tests and assays of the drug made during the manufacture of the batch and after it is packaged; and (3) the laboratory facilities used in such controls.

Such initial request shall also be preceded or accompanied by the key of the batch marks used by such person and by specimens of all labeling (including specimens of all brochures and other printed matter except readily available medical publications, referred to in such labeling) to be used for such drug. When any change is made in any such facility or control, or in any such key or labeling, such person shall promptly submit to the Commissioner a full statement of such change or, in the case of changed labeling, specimens showing all such changes.

(c) Each sample submitted pursuant to the regulations in this part shall be addressed to the Commissioner. Its package shall be clearly identified as to its contents and shall bear the name and post-office address of the person submitting it.

(d) In addition to the information and samples specifically required to be submitted to the Commissioner by the regulations in this part, the person who requests certification of a batch shall submit such further information and samples as the Commissioner may require for the purpose of investigations to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate.

(e) Upon the request of any person, stating reasonable grounds therefor, the Commissioner shall furnish such person with a portion of the working standards.

§ 146.3 *Certification.* (a) If it appears to the Commissioner, after such investigation as he considers necessary, that:

(1) The information (including results of tests and assays) and samples required by or pursuant to the regulations in this part have been submitted, and the request for certification contains no untrue statement of a material fact; and

(2) The batch complies with the regulations in this part and conforms to the applicable standards of identity, strength, quality, and purity prescribed by the regulations in this part; the Commissioner shall certify that such batch is safe and efficacious for use, subject to such conditions on the effectiveness of certificates as are prescribed by § 146.4, and shall issue to the person who requested it a certificate to that effect.

(b) If the Commissioner determines, after such investigation as he considers to be necessary, that the information submitted pursuant to the regulations in this part, or the batch covered by such request, does not comply with the requirements set forth in paragraph (a) of this section for the issuance of a certificate, the Commissioner shall refuse to certify such batch and shall give notice thereof to the person who requested certification, stating his reasons for refusal.

(c) Compliance of a drug with the standards of identity, strength, quality, and purity prescribed by regulations in this part shall be determined by the tests and methods of assay prescribed for such drug by regulations in Part 141 of this chapter.

§ 146.4 *Conditions on the effectiveness of certificates.* (a) A certificate shall not become effective:

(1) If it is obtained through fraud or through misrepresentation or concealment of a material fact;

(2) With respect to any package unless in complies with the packaging requirements, if any, prescribed by the regulations in this part which were in effect on the date of the certificate;

(3) With respect to any package unless its label and labeling bear all words, statements, and other information required by the regulations in this part; or

(4) With respect to any package of penicillin or streptomycin when it is included in a packaged combination with another drug, unless such other drug complies with the requirements of the regulations in this part.

(b) A certificate shall cease to be effective:

(1) With respect to any immediate container after the expiration date, if any, prescribed by the regulations in this part;

(2) With respect to any immediate container when it or its seal (if the regulations in this part require it to be sealed) is broken, or when its label or labeling ceases to conform to any labeling requirement prescribed by the regulations in this part, except that:

(i) If the drug in such container is repacked or used as an ingredient in the manufacture of another drug, and certification of the batch thus made is requested, such certificate shall continue to be effective for a reasonable time to permit certification or destruction of such batch; or

(ii) If the drug is in a container packaged for dispensing and is used in compounding a prescription issued in his professional practice by a physician, dentist, or veterinarian licensed by law to administer or apply drugs, such certificate shall continue to be effective for a reasonable time to permit the delivery of the drug compounded on such prescription;

(3) With respect to any immediate container of penicillin when it is included in the packaged combination penicillin with aluminum hydroxide gel or a vasoconstrictor, except that when certification of the batch so included is requested such certificate shall continue to be effective for a reasonable time to permit certification of such batch which is a part of such combination;

(4) With respect to any package when the drug therein fails to meet the standards of identity, strength, quality, and purity which were in effect on the date of the certificate; except that those minor changes which occur before the expiration date and which are normal and unavoidable in good storage and distribution practice shall be disregarded;

(5) With respect to any package of penicillin or streptomycin included in a packaged combination with another drug, when such other drug fails to meet the requirements of the regulations in this part; or

(6) With respect to any immediate container, if such regulations require its labeling to bear a caution against dispensing otherwise than on prescription, at the beginning of the act of dispensing or offering to dispense it otherwise than:

(i) By physician, dentist, or veterinarian, in his professional practice, who is licensed by law to administer drugs; or

(ii) On his prescription issued in his professional practice.

§ 146.5 *Records of distribution.* (a) The person who requested certification shall keep complete records showing each shipment and other delivery (including exports) of each certified batch or part thereof by such person or by any person subject to his control. Such records shall show the date and quantity of each such shipment or delivery and the name and post-office address of the person to whom such shipment or delivery was made, and shall be kept for not less than three years after such date.

(b) Upon the request of any officer or employee of the Food and Drug Administration, or of any other officer or employee of the United States acting on behalf of the Administrator, the person to whom a certificate is issued shall at all reasonable hours make such records available to any such officer or employee and shall accord to him full opporunity to make inventory of stocks of such batch on hand and otherwise to check the correctness of such records.

§ 146.6 *Authority to refuse certification service.* When the Administrator finds, after giving notice and opportunity for hearing, that a person has:

(a) Obtained or attempted to obtain a certificate through fraud, or through misrepresentation or concealment of a material fact;

(b) Falsified the records required to be kept by § 146.5; or

(c) Failed to keep such records or to make them available, or to accord full opportunity to make an inventory of stocks on hand or otherwise to check the correctness of such records, as required by § 146.5, and such failure may materially impair the certification service; the Administrator will immediately suspend service to such person under the regulations in this part and will continue such suspension unless and until such person shows adequate cause why such service should be resumed.

§ 146.7 *New penicillin or streptomycin products.* Any request that the Administrator provide for the certification of batches of a drug for which no provision for certification is made in the existing regulations in this part shall be in form specified by the Commissioner and shall be accompanied by:

(a) A statement of the conditions for which the person who makes such request intends such drug to be used, and adequate directions for use in each such condition;

(b) Full reports of investigations which have been made to show whether or not such drug is safe and efficacious for use in such conditions;

(c) A full list of the articles used as components of such drug;

(d) A full statement of the composition of such drug;

(e) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

(f) A full description of, or references to publications containing practical and accurate tests and methods of assay to determine the identity, strength, quality, and purity of such drug;

(g) Such samples of such drug and of the articles used as components thereof as the Commissioner may require; and

(h) Specimens of all labeling (including all brochures and other printed matter, except readily available medical publications, referred to in such labeling) proposed to be used for such drug.

§ 146.8 *Fees.* (a) Fees for the services rendered under the regulations in this part shall be such as are necessary to provide, equip, and maintain an adequate certification service.

(b) The fee for such services with respect to each batch of a drug, certification of which is provided by the regulations in this part, is the fee prescribed in the section relating specifically to such drug, except that, in case of a supplemental request submitted pursuant to the provisions of § 146.18, the fee shall be $2.00.

(c) When the Commissioner considers it necessary to make investigations of a new penicillin or streptomycin product, on which a request has been submitted in accordance with § 146.7, the fee for such service shall be the cost thereof. In such case the request shall be followed by an advance deposit in such amount as the Commissioner specifies, and thereafter such additional advance deposits shall be made as the Commissioner estimates may be necessary to prevent arrears in the payment of such fee.

(d) A person requiring continuing certification services may maintain an advance deposit of the estimated cost of such services for a two-month period. Such deposit shall be debited with fees for services rendered, but shall not be debited for any fee the amount of which is not definitely specified in the regulations in this part unless the depositor has previously requested the performance of the services to be covered by such fee. A monthly statement for each such advance deposit shall be rendered.

(e) The unearned portion of any advance deposit shall be refunded to the depositor upon his application.

(f) All deposits and fees required by the regulations in this part shall be paid

by money order, bank draft, or certified check drawn to the order of the Treasurer of the United States, collectible at par, at Washington, D. C.

(g) All earned fees shall be deposited in the Treasury of the United States to the credit of Miscellaneous Receipts, Federal Security Agency.

NOTE: Sections 146.9 to 146.17, inclusive, reserved for future provisions.

§ 146.18 *Exemptions for labeling.* (a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of a drug which is to be labeled at an establishment located elsewhere than at the place of manufacture shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from the requirements of section 502 (l) of the act if the labeling of each shipping container bears the batch mark of the drug and the number of units per package, and if the person who introduced such shipment or delivery into interstate commerce holds a permit from the Commissioner authorizing shipment for labeling in such establishment.

(b) (1) An application for such a permit shall be in a form specified by the Commissioner, and shall give the name and location of the establishment in which such labeling is to be done.

(2) In case the applicant is the operator of such establishment, the application shall include a written agreement signed by him that he will request certification of each batch from which any shipment or delivery is made to such establishment unless it is exempt under section 801 (d) of the act or § 146.23; that he will not remove any of such drug from such establishment unless it complies with section 502 (l) of the act or is so exempt, or if certification is refused, unless it is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured; that he will keep complete records showing the date, quantity, and batch mark of each such shipment and delivery and the disposition thereof; that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such disposition; and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records.

(3) In case the applicant is not the operator of such establishment such application shall include or be accompanied by:

(i) A written agreement signed by the applicant that he will request certification of each batch from which any shipment or delivery is made to such establishment unless it is exempt under section 801 (d) of the act or § 146.23; that he will keep complete records showing the date, quantity, and batch mark of each such shipment and delivery; and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such shipment or delivery; and

(ii) A written agreement signed by the operator of such establishment that he will submit a request, supplemental to that of the applicant, for the certification of each batch or portion thereof comprised in any such shipment or delivery received by him unless it is exempt under section 801 (d) of the act or § 146.23; that he will specify in his request the number of packages of each size in such shipment or delivery, the date of delivery, the batch mark thereof, and the batch mark he will use therefor; that the batch marks to be used (if different from those of the applicant) will be only those of which the key is specified in this agreement; that the labeling to be used for such packages will be only that of which specimens are attached to this agreement (including specimens of all brochures and other printed matter, except readily available medical publications, referred to in such labeling); that when any change is made in such key or labeling he will promptly submit to the Commissioner a full statement of such change or, in the case of changed labeling, specimens showing all such changes; that he will not remove any of such drug from such establishment unless it complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or § 146.23 or, if certification is refused, unless it is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured; that he will keep complete records of the disposition of each such shipment and delivery; that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such disposition; and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records.

(4) When the Commissioner finds, after giving notice and opportunity for hearing, that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such establishment, shall become void ab initio at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after labeling, from such establishment unless such batch complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or § 146.23 or, if certification is refused, unless such shipment or delivery is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

(d) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is not the operator of such establishment, shall expire at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after labeling, from such establishment unless such batch complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or § 146.23 or, if certification is refused, unless such shipment or delivery, within a reasonable time, is destroyed or returned to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

§ 146.19 *Exemptions for storage.* (a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of a drug which is to be stored at a warehouse located elsewhere than at the place of manufacture shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such warehouse, from the requirements of section 502 (l) of the act if the labeling of each shipping container bears the batch mark of the drug, and if the person who introduced such shipment or delivery into interstate commerce holds a permit from the Commissioner authorizing shipment for storage in such warehouse.

(b) An application for such a permit shall be in a form specified by the Commissioner, and shall give the name and location of the warehouse in which such drug is to be stored. Such application shall be accompanied by:

(1) A written agreement signed by the applicant that he will request certification of each batch thereof unless it is exempt under section 801 (d) of the act or §§ 146.18, 146.21, or 146.22, that he will not remove any of such drug from such warehouse unless it complies with section 502 (l) of the act or is so exempt or, if certification is refused unless it is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured; that he will keep complete records showing the date, quantity, and batch mark of each shipment and other delivery of any such drug to such warehouse, and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such shipment or delivery; and

(2) A written statement signed by the operator of such warehouse showing that he has adequate facilities for such storage; such statement shall contain an agreement that he will hold each shipment or other delivery of such drug intact, under such conditions as will not cause failure of the drug to comply with the requirements for certification, that he will keep complete records showing the date of receipt by him and the quantity and batch mark of each such shipment and delivery and the disposition thereof, that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years

after the date of such disposition, and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records.

If the applicant keeps complete records showing the date, quantity, and batch mark of each shipment and other delivery of any such drug from such warehouse and the name and post-office address of the person to whom such shipment or delivery was made, the agreement to keep records of such disposals, to make such records available, and to afford opportunity for checking their correctness may be included in the applicant's agreement and omitted from that of the operator.

When the Commissioner finds, after giving notice and opportunity for hearing, that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such warehouse, shall become void ab initio at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof from such warehouse unless such batch complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or §§ 146.18, 146.21, or 146.22, or, if certification is refused, unless such shipment or delivery is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

(d) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is not the operator of such warehouse, shall expire at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof from such warehouse unless such batch complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or §§ 146.18, 146.21, or 146.22, or, if certification is refused, unless such shipment or delivery, within a reasonable time, is destroyed, or returned to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

§ 146.20 *Exemptions for processing.* (a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of penicillin or streptomycin in concentrated aqueous solution which is to be processed at an establishment located elsewhere than at the place of manufacture, shall be exempt during the time of introduction into and movement in interstate commerce and the time of holding in such establishment from the requirements of section 502 (l) of the act if the person who introduced such shipment or delivery into interstate commerce holds a permit from the Commissioner authorizing shipment for processing in such establishment, and each package of such solution bears the batch mark of the drug.

(b) An application for such a permit shall be in a form specified by the Commissioner and shall give the name and location of the establishment in which such processing is to be done. Such application shall be accompanied by:

(1) A written agreement signed by the applicant that he will keep complete records showing the date, quantity, potency, and batch mark of each shipment and other delivery of any such solution to such establishment, and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such shipment or delivery;

(2) A written statement signed by the operator of such establishment showing that he has adequate facilities for such processing; such statement shall contain an agreement that he will keep complete records showing the date of receipt by him and the quantity and batch mark of each such shipment and delivery and the disposition thereof, that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after date of such disposition, and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records; and

(3) A written agreement signed by the person who will own the drug after the processing is completed that he will request certification of each batch thereof unless it is exempt under section 801 (d) of the act or §§ 146.18, 146.19, 146.21, 146.22, or 146.23, and that he will not remove any of such drug from such establishment unless it complies with section 502 (l) of the act or is so exempt.

When the Commissioner finds, after giving notice and opportunity for hearing, that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such establishment, shall become void ab initio at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after processing, from such establishment unless the batch made from such shipment or delivery complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or §§ 146.18, 146.19, 146.21, 146.22, or 146.23 or, if certification is refused, unless such shipment or delivery is reprocessed and certified or destroyed within a reasonable time.

(d) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is not the operator of such establishment, shall expire at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after processing, from such establishment unless the batch made from such shipment or delivery complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or §§ 146.18, 146.19, 146.21, 146.22, or 146.23, or, if certification has been refused, unless such shipment or delivery is reprocessed and certified or destroyed within a reasonable time.

§ 146.21 *Exemptions for repacking.* (a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of a drug which is to be repacked at an establishment located elsewhere than at the place of manufacture shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment from the requirements of section 502 (l) of the act if the labeling of each container bears the batch mark of the drug and the number of units per package, and if the person who introduced such shipment or delivery into interstate commerce holds a permit from the Commissioner authorizing shipment for repacking in such establishment.

(b) An application for such a permit shall be in a form specified by the Commissioner, and shall give the name and location of the establishment in which such repacking is to be done. Such application shall be accompanied by:

(1) A written agreement signed by the applicant that he will keep complete records showing the date, quantity, and batch mark of each shipment and other delivery of any such drug to such establishment, and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of each shipment or delivery;

(2) A written statement signed by the operator of such establishment showing that he has adequate facilities for such repacking; such statement shall contain an agreement that he will keep complete records showing the date of receipt by him and the quantity and batch mark of each such shipment and delivery and the disposition thereof, that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such disposition, and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records; and

(3) A written agreement signed by the person who will own the drug after the repacking is completed that he will request certification of each batch thereof unless it is exempt under section 801 (d) of the act or §§ 146.18, 146.19, or 146.23, and that he will not remove any of such drug from such establishment unless it complies with section 502 (l) of the act or is so exempt or is returned to him for labeling or, if certification is refused, unless it is returned within a reasonable time to permit reprocessing and certification, destruction, or such

exemption at the establishment where it was manufactured.

When the Commissioner finds, after giving notice and opportunity for hearing, that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such establishment, shall become void ab initio at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after repacking, from such establishment unless such batch complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or §§ 146.18, 146.19, or 146.23 or is returned to such person for labeling or, if certification is refused, unless such shipment or delivery is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

(d) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is not the operator of such establishment, shall expire at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after repacking, from such establishment unless such batch complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or §§ 146.18, 146.19, or 146.23 or is returned to such person for labeling or, if certification is refused, unless such shipment or delivery, within a reasonable time, is destroyed or returned to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

§ 146.22 *Exemptions for manufacturing use.* (a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of penicillin or streptomycin which is packed in containers of not less than ten million units of penicillin or 10 grams of streptomycin each shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in the establishment where it is so used, from the requirements of section 502 (l) of the act if it conforms to the standards prescribed therefor by the section of the regulations in this part which is specifically applicable to such other drug, if the label of each container bears the batch mark of the drug, the number of units or grams per package, and the date on which the latest assay of the drug was completed, and if the person who introduced such shipment or delivery into interstate commerce holds a permit from the Commissioner authorizing shipment for manufacturing use in such establishment.

(b) An application for such a permit shall be in a form specified by the Commissioner, shall give the name and location of the establishment in which such drug is to be used and shall be accompanied by:

(1) A written agreement signed by the applicant that he will keep complete records showing the date, quantity, and batch mark of each shipment and other delivery of any such drug to such establishment, and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such shipment or delivery;

(2) A written statement signed by the operator of such establishment showing that he has adequate facilities for the manufacture of such other drug; such statement shall contain an agreement that he will keep complete records showing the date of receipt by him and the quantity and batch mark of each such shipment and delivery and the disposition thereof and showing the quantity and batch mark of each batch of such other drug manufactured by him and the disposition thereof; that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such disposition, and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records; and

(3) A written agreement signed by the person who will own the drug after its manufacture is completed that he will request certification of each batch thereof unless it is exempt under section 801 (d) of the act or §§ 146.18, 146.19, 146.21, or 146.23, and that he will not remove any of such drug from such establishment unless it complies with section 502 (l) of the act or is so exempt or is returned to him for labeling.

When the Commissioner finds, after giving notice and opportunity for hearing, that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such establishment, shall become void ab initio at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof from such establishment, prior to its use in the manufacture of another drug, unless it is exempt under section 801 (d) of the act.

(d) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is not the operator of such establishment, shall expire at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof from such establishment, prior to its use in the manufacture of another drug, unless it is exempt under section 801 (d) of the act.

§ 146.23 *Exemptions for investigational use.* (a) A shipment or other delivery of a drug shall be exempt from section 502 (l) of the act if all of the following requirements are complied with:

(1) The label of such drug bears the batch mark and the statement "Caution—Limited by Federal Law to investigational use only."

(2) Such shipment or delivery is made only to, and solely for investigational use by or under the direction of, an expert qualified by scientific training and experience to investigate the safety or efficacy of such drug.

(3) The person who introduced such shipment or delivery into interstate commerce keeps complete records showing the date, quantity, and batch mark of each such shipment and delivery.

(4) Such person, prior to making such shipment or delivery, obtains a statement signed by such expert showing that he has adequate facilities for the investigation to be conducted by him, and that such drug will be used solely by him or under his direction for the investigation. Such person shall keep such statement.

(5) Such person makes all documents referred to in subparagraphs (3) and (4) of this paragraph available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such shipment or delivery.

(b) An exemption of a shipment or other delivery of a drug under paragraph (a) of this section shall become void ab initio if:

(1) The person who introduced such shipment or delivery into interstate commerce fails to keep any document required to be kept by paragraph (a) of this section; or

(2) Such person fails to make any such document available for inspection as required by paragraph (a) of this section.

(c) An exemption of a shipment or other delivery of a drug under paragraph (a) of this section shall expire upon the use of any part of such shipment or delivery other than in accordance with the signed statement referred to in subparagraph (4) of paragraph (a) of this section.

§ 146.24 *Sodium penicillin (penicillin sodium, penicillin sodium salt), calcium penicillin (penicillin calcium, penicillin calcium salt), crystalline penicillin (crystalline penicillin sodium, crystalline penicillin sodium salt, crystalline penicillin potassium, crystalline penicillin potassium salt, crystalline penicillin G sodium, crystalline penicillin G sodium salt, crystalline penicillin G potassium, crystalline penicillin G potassium salt)*—(a) *Standards of identity, strength, quality, and purity.* Sodium penicillin is the sodium salt of a kind of penicillin, or a mixture of two or more such salts; calcium penicillin is the calcium salt of a kind of penicillin, or a mixture of two or more such salts; crystalline penicillin is the heat stable crystalline sodium or potassium salt of one or more kinds of penicillin, but the quantity of any salt of penicillin K therein is not more than 30 percent; crystalline penicillin G is

crystalline penicillin which contains not less than 90 percent of the sodium salt or potassium salt of penicillin G. Each such drug is so purified and dried that:

(1) Its potency is not less than 500 units per milligram, except that:

(i) If it contains not less than 90 percent of a salt of penicillin X its potency is not less than 350 units per milligram;

(ii) If it is crystalline penicillin G sodium its potency is not less than 1500 units per milligram; and

(iii) If it is crystalline penicillin G potassium its potency is not less than 1435 units per milligram;

(2) It is sterile;

(3) It is nontoxic;

(4) It is nonpyrogenic;

(5) Its moisture content is not more than 2.5 percent unless it is crystalline penicillin in which case its moisture content is not more than 1.5 percent;

(6) Its pH in aqueous solution of 5,000 to 10,000 units per milliliter is not less than 5.0 and not more than 7.5;

(7) Its solution in water for injection U. S. P., dextrose injection 5 percent U. S. P., or physiological salt solution U. S. P., prepared by adding 5,000 to 10,000 units per milliliter, is of such clarity that it is substantially free of any turbidity or undissolved material.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing it shall be in immediate containers of colorless transparent glass which meet the test for glass containers of type I or type II prescribed by the U. S. P., closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness; each such container shall contain 100,000 units, 200,000 units, 500,000 units, 1,000,000 units or 5,000,000 units, except that when packaged and labeled solely for dental use each such container may contain 10,000 units or 20,000 units, and each may be packaged in combination with a container of the solvent, water for injection U. S. P., dextrose injection 5-percent U. S. P. (if not packaged for dental use), or physiological salt solution U. S. P.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in the immediate container;

(iii) The statement "Expiration date _____", the blank being filled in with the date which is 18 months or if it is crystalline penicillin 36 months, after the month during which the batch was certified; and

(iv) The statement "For Manufacturing Use", "For Repacking", or "For Manufacturing Use or Repacking" when packaged for repacking or for use as an ingredient in the manufacture of another drug, as the case may be.

(2) On the outside wrapper or container if it is not crystalline penicillin the statement "Store in refrigerator not above 15° C. (59° F.)", or "Store below 15° C. (59° F.)".

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing, adequate directions for use and warnings as required by section 502 (f) of the act, including:

(i) Clinical indications;

(ii) Dosage and administration, including method of preparation and strength of solutions for different routes of injection and local application;

(iii) The conditions under which such solutions should be stored, including a reference to their instability when stored under other conditions and if it is crystalline penicillin the statement "Sterile solution may be kept in refrigerator for three days without significant loss of potency," and if it is not crystalline penicillin the statement "Sterile solution may be kept in refrigerator for one week without significant loss of potency";

(iv) Contraindications; and

(v) Untoward effects that may accompany administration, including sensitization.

If two or more immediate containers are in such package, the number of such circulars or other labeling shall not be less than the number of such containers.

(d) *Requests for certification, check tests and assays; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of units in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, sterility, toxicity, pyrogens, moisture, pH, clarity, penicillin K content (unless it is crystalline penicillin G), crystallinity and heat stability if it is crystalline penicillin, and the penicillin G content if it is crystalline penicillin G. If such batch or any part thereof is to be packaged with a solvent such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) If such batch is packaged for dispensing such person shall submit with his request a sample consisting of one immediate container for each 5,000 immediate containers in such batch, but in no case shall such sample consist of less than six or more than 13 immediate containers, unless:

(i) It is crystalline penicillin, other than crystalline penicillin G, then not less than 8 and not more than 15 immediate containers;

(ii) It is crystalline penicillin G, then not less than 10 and not more than 17 immediate containers;

(iii) It is packaged in containers of 10,000 units or 20,000 units for dental use, then not less than 20 and not more than 100 immediate containers if it is not crystalline penicillin and not less than 40 and not more than 100 immediate containers if it is crystalline penicillin. Such sample shall be collected by taking single immediate containers, before or after labeling, at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(3) If such batch is packaged for repacking or for use as an ingredient in the manufacture of another drug, such person shall submit with his request a sample containing 6, or in the case of crystalline penicillin 10, approximately equal portions of at least 40 milligrams each taken from different parts of such batch; each such portion shall be packaged in a separate container, and in accordance with the requirements of paragraph (b) of this section.

(4) In connection with contemplated requests for certification of repacked batches or batches of another drug in the manufacture of which it is to be used, the manufacturer of a batch which is to be so repacked or used may request the Commissioner to make check tests and assays on a sample of such batch taken as prescribed by subparagraph (3) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraphs (d) (2), (3), and (4) of this section, except if packaged in containers of 10,000 units or 20,000 units each for dental use, $1.00 for each immediate container; and

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.25 *Penicillin in oil and wax (calcium penicillin in oil and wax, crystalline penicillin in oil and wax)*—(a) *Standards of identity, strength, quality, and purity.* Penicillin in oil and wax is a suspension of calcium penicillin or crystalline penicillin in a menstruum of refined peanut oil or sesame oil in which white wax is dispersed. Its potency is 100,000 units, 200,000 units, or 300,000 units per milliliter except if it

is packaged and labeled solely for udder instillations of cattle its potency is 2,000 units per milliliter. The content of white wax in the menstruum before the addition of the penicillin is not less than 3.0 percent (w/v) if the potency is to be not more than 200,000 units per milliliter, and not less than 4.7 or more than 4.9 percent (w/v) if the potency is to be 300,000 units per milliliter. Its moisture content is not more than 1.0 percent. It is sterile. The calcium penicillin or crystalline penicillin used conforms to the requirements of § 146.24 (a) except subparagraph (7), but its potency is not less than 750 units per milligram if it is used in making a product of not more than 200,000 units per milliliter, and not less than 900 units per milligram if it is used in making a product containing 300,000 units per milliliter. The sesame oil used conforms to the standards prescribed therefor by the N. F. The white wax used conforms to the standards prescribed therefor by the U. S. P.

(b) *Packaging.* The immediate container of penicillin in oil and wax shall be of colorless transparent glass (unless it is packaged and labeled solely for udder instillations of cattle) so closed as to be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that its contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The quantity of penicillin in oil and wax in each such container shall be such that as much as one milliliter but not more than 20 milliliters may be withdrawn therefrom, unless it is packaged for repacking or is packaged and labeled solely for udder instillations of cattle.

(c) *Labeling.* Each package of penicillin in oil and wax shall bear, on its label or labeling as hereinafter indicated the following:

(1) On the outside wrapper or container and the immediate container of the package:

(i) The batch mark;

(ii) The number of units per milliliter of the batch;

(iii) The statement "Expiration date _____," the blank being filled in, if crystalline penicillin is used, with the date which is 18 months, or if crystalline penicillin is not used, with the date which is 12 months after the month during which the batch was certified;

(iv) The statement "For intramuscular or subcutaneous use only"; and

(v) If it is represented to contain 2,000 units per milliliter, the statement "For udder instillations of cattle only".

(2) On the circular or other labeling within or attached to the package, adequate directions for use and warnings as required by section 502 (f) of the act, including:

(i) Clinical indications;

(ii) Dosage and administration, including site of injection;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration, including sensitization.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of penicillin in oil and wax shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each of such packages, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that the peanut oil or sesame oil and white wax used in making such batch conform to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, moisture.

(ii) The penicillin used in making the batch; potency, sterility, toxicity, pyrogens, moisture, pH, penicillin K content (unless it is crystalline penicillin G), crystallinity and heat stability if it is crystalline penicillin, and the penicillin G content if it is crystalline penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one package for each 500 packages in the batch, but in no case less than three packages or more than 12 packages, collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The penicillin used in making the batch; six packages if it is calcium penicillin or 10 packages if it is crystalline penicillin, containing approximately equal portions of not less than 40 milligrams each, packaged in accordance with the requirements of § 146.24 (b).

(iii) In case of an initial request for certification, the peanut oil or sesame oil and white wax used in making the batch; one package of each containing, respectively approximately 250 grams and 25 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin in oil and wax under the regulations in this part shall be:

(1) $8.00 for each package submitted in accordance with paragraph (d) (3) (i), $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii), of this section; and

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fees prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.26 *Penicillin ointment (calcium penicillin ointment, penicillin ointment calcium salt).*—(a) *Standards of identity, strength, quality, and purity.* Penicillin ointment is calcium penicillin in an ointment base composed of wool fat, petrolatum, or white petrolatum, or any mixture of two or all of these, with or without liquid petrolatum, white wax, yellow wax, cottonseed oil, or peanut oil, oxycholesterin derivatives from wool fat, or any mixture of two or all of these. Its moisture content is not more than 1.0 percent. Its potency is not less than 250 units per gram. Its content of viable microorganisms is not more than 50 per gram. The penicillin used conforms to the requirements of § 146.24 (a) except the limitation on penicillin K content and except subparagraphs (1), (2), (4), and (7) of § 146.24 (a), but its potency is not less than 300 units per milligram. The peanut oil is refined; each other component of the ointment base conforms to the standards prescribed therefor by the U. S. P.

(b) *Packaging.* Penicillin ointment shall be packaged in collapsible tubes, which shall be well-closed containers as defined by the U. S. P., and shall not be larger than the one-eight-ounce size if such ointment is represented for ophthalmic use and in no case larger than the two-ounce size. The composition of the tubes and closure shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of penicillin ointment shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units per gram of the batch; and

(iii) The statement "Expiration date _____," the blank being filled in with the date which is nine months after the month during which the batch was certified.

(2) On the outside wrapper or container:

(i) The statement "Store in refrigerator not above 15° C. (59° F.)," or "Store below 15° C. (59° F.);"

(ii) Unless it is intended solely for veterinary use and is conspicuously so labeled, the statement "Caution: To be

dispensed only by or on the prescription of a _____," the blank being filled in with the word "physician" or "dentist" or "veterinarian" or with any combination of two or all of these words as the case may be; and

(iii) Unless the drug is intended solely for veterinary use and is so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such ointment; or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure or printed matter will be sent on request.

(3) On the circular or other labeling within or attached to the package, if the drug is intended solely for veterinary use, directions and precautions adequate for the use of such ointment, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of penicillin ointment shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that each component of the ointment base used conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, moisture, microorganism count.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one package for each 5,000 packages in the batch, but in no case less than five packages or more than 12 packages, collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The penicillin used in making the batch; five packages containing approximately equal portions of not less than 40 milligrams each, packaged in accordance with the requirements of § 146.24 (b).

(iii) In case of an initial request for certification, the ingredients used in making the ointment base of the batch; one package of each containing approximately 200 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin ointment under the regulations in this part shall be:

(1) $8.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i) of this section, $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii), of this section; and

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with §146.8 (d).

§ 146.27 *Tablets buffered penicillin (tablets buffered penicillin sodium, tablets buffered penicillin calcium, tablets buffered penicillin potassium, tablets buffered penicillin sodium salt, tablets buffered penicillin calcium salt, tablets buffered penicillin potassium salt).*—(a) *Standards of identity, strength, quality, and purity.* Tablets buffered penicillin is penicillin and one or more of the buffer substances sodium citrate, sodium benzoate, citric acid, aluminum hydroxide, calcium carbonate, magnesium oxide, aluminum dihydroxyamino acetate, and sodium salts of fatty acids if in quantities sufficient to exert a buffering action. It is tableted with or without the addition of one or more suitable and harmless diluents, binders, lubricants, colorings, and flavorings. The potency of each tablet is not less than 50,000 units and if it is less than 100,000 units it is "unscored"; its moisture content is not more than 1.0 percent. The penicillin used conforms to the standards prescribed therefor by §146.24 (a), except subparagraphs (1), (2), (4), and (7) of § 146.24 (a), but its potency is not less than 300 units per milligram. Each other substance, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each tablet buffered penicillin is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the tablets by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the content beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The number of tablets in the immediate container is such that the total number of units therein is not less than 300,000.

(c) *Labeling.* Each package of tablets buffered penicillin shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in each tablet of the batch;

(iii) The name of each buffer substance used in making the batch; and

(iv) The statement "Expiration date _____", the blank being filled in, if crystalline penicillin is used, with the date which is 18 months, or if crystalline penicillin is not used, with the date which is 12 months after the month during which the batch was certified.

(2) On the outside wrapper or container:

(i) Unless it is intended solely for veterinary use and is conspicuously so labeled, the statement "Caution: To be dispensed only by or on the prescription of a _____", the blank being filled in with the word "physician" or "dentist" or "veterinarian" or any combination of two or all of these words, as the case may be.

(ii) Unless it is intended solely for veterinary use and is so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such tablets buffered penicillin, or a reference to a brochure, or other printed matter containing such directions and precautions, and a statement that such brochure and printed matter will be sent on request.

(3) On the circular or other labeling within or attached to the package, if it is intended solely for veterinary use, directions and precautions adequate for the use of such tablets, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration, including those from any buffer substance present.

If two or more such immediate containers are in such package the number of such circulars or other labeling shall not be less than the number of such containers.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of tablets buffered penicillin shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each tablet, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed and a statement that each ingredient used in

making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per tablet, average moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, penicillin K content (unless it is crystalline penicillin G), crystallinity and heat stability if it is crystalline penicillin, and the penicillin G content if it is crystalline penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one tablet for each 5,000 tablets in the batch, but in no case less than 20 tablets or more than 100 tablets, collected by taking single tablets at such intervals throughout the entire time of tableting that the quantities tableted during the intervals are approximately equal.

(ii) The penicillin used in making the batch; six packages, or in the case of crystalline penicillin 10 packages, each containing approximately equal portions of not less than 40 milligrams each, packaged in accordance with the requirements of § 146.24 (b).

(iii) In case of an initial request for certification, each buffer substance, diluent, binder, lubricant, coloring, and flavoring used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of tablets buffered penicillin under the regulations in this part shall be:

(1) $1.00 for each tablet in the sample submitted in accordance with paragraph (d) (3) (i) of this section. $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii), of this section; and

(2) If the Commissioner considers that investigations, other than examination of such tablets and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.29 *Penicillin with aluminum hydroxide gel*—(a) *Standards of identity, strength, quality, and purity.* Penicillin with aluminum hydroxide gel is a packaged combination of one immediate container of penicillin and one immediate container of aluminum hydroxide gel. Such penicillin conforms to the standards prescribed therefor by § 146.24 (a), except subparagraphs (1), (4), and (7) of § 146.24 (a), but its potency is not less than 300 units per milligram. Such aluminum hydroxide gel conforms to the standards prescribed therefor by the U. S. P., but contains not more than 50 viable microorganisms per milliliter.

(b) *Packaging.* The immediate container of the penicillin shall conform to the packaging requirements set forth in § 146.24 (b), except that it shall contain not less than 300,000 units and its closure may be one through which a hypodermic needle cannot be introduced. The immediate container of the aluminum hydroxide gel shall be a tight container as defined by the U. S. P.; the quantity therein shall be 30 milliliters for each 100,000 units in the immediate container of penicillin.

(c) *Labeling.* Each package of penicillin with aluminum hydroxide gel shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and on the immediate container of the penicillin:

(i) The batch mark;

(ii) The number of units in such container; and

(iii) The statement "Expiration date _____", the blank being filled in with the date which is 18 months after the month during which the batch was certified, unless it is crystalline penicillin, in which case the blank is filled in with the date which is 36 months after the month during which the batch was certified.

(2) On the immediate container of the penicillin, the statement "Warning—Not for injection", unless it conforms to the standards and packaging requirements prescribed therefor by § 146.24 (a) and (b), except that the immediate container may contain 300,000 units.

(3) On the outside wrapper or container of the package, the statements:

(i) "Caution: To be dispensed only by or on the prescription of a ", the blank being filled in with the word "physician" or "dentist" or both as the case may be; and

(ii) "Store in refrigerator not above 15° C. (59° F.)", or "Store below 15° C. (59° F.)", unless it is crystalline penicillin in which case the storage statement may be omitted.

(4) On the circular or other labeling within or attached to the package, directions and precautions adequate for the use of such combination, including:

(i) Clinical indications;

(ii) Dosage and administration, including methods of mixing the penicillin with the aluminum hydroxide gel;

(iii) The conditions under which the mixture should be stored, including a reference to its instability when stored under other conditions and the statement "The mixture may be kept in refrigerator for one week without significant loss of potency";

(iv) Contraindications; and

(v) Untoward effects that may accompany administration.

(d) *Requests for certification; samples.* (1) In addition to complying with requirements of § 146.2, a person who requests certification of a batch of penicillin for inclusion in such combination shall submit with his request a statement showing the batch mark of the penicillin, the number of packages thereof in such batch, the number of units in the immediate container thereof, and (unless it was previously submitted) the date on which the latest assay of the penicillin included in such combination was completed, and a statement that the aluminum hydroxide gel conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays made by him on an accurately representative sample of the penicillin for potency, sterility, toxicity, moisture, pH, penicillin K content (unless it is crystalline penicillin G), crystallinity and heat stability if it is crystalline penicillin, and the penicillin G content if it is crystalline penicillin G.

(3) If the penicillin has not been certified previously, such person shall submit in connection with his request a sample of the batch consisting of one package for each 5,000 packages in the batch, but in no case less than six or more than 13 packages except that in the case of crystalline penicillin other than crystalline penicillin G such sample shall consist of not less than eight and not more than 15 packages, and in the case of crystalline penicillin G not less than 10 and not more than 17 packages. Such sample shall be collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(4) No result referred to in subparagraph (2) of this paragraph is required if such result has been previously submitted.

(e) *Fees.* The fees for the services rendered with respect to each batch of penicillin for inclusion in combination with aluminum hydroxide gel under the regulations of this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) (3) of this section, or $2.00 if no such sample is submitted, and

(2) If the Commissioner considers that investigations, other than examination of such containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.30 *Penicillin troches (sodium penicillin troches, calcium penicillin troches, potassium penicillin troches, penicillin troches sodium salt, penicillin troches calcium salt, penicillin troches potassium salt)*—(a) *Standards of identity, strength, quality, and purity.* Peni-

cillin troches are troches composed of penicillin and one or more suitable and harmless diluents, binders, and lubricants, with or without one or more suitable and harmless masticatory substances, colorings, and flavorings. The potency of each troche is not less than 500 units; the moisture content is not more than 1.0 percent. The penicillin used conforms to the requirements of § 146.24 (a) except the limitation on penicillin K content and except subparagraphs (1), (2), (4), and (7) of § 146.24 (a), but the potency is not less than 300 units per milligram. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each penicillin troche is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the troches by a plug of cotton or other like material. The composition of the immediate container, or foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of penicillin troches shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in each troche of the batch; and

(iii) The statement "Expiration date ____," the blank being filled in with the date which is nine months after the month during which the batch was certified.

(2) On the outside wrapper or container:

(i) The statement "Store in refrigerator not above 15° C. (59° F.)," or "Store below 15° C. (59° F.)";

(ii) The statement "Caution: To be dispensed only by or on the prescription of a ____," the blank being filled in with the word "physician" or "dentist" or both, as the case may be; and

(iii) A reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such troches; or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure and printed matter will be sent on request.

(3) On the label and labeling if a masticatory substance is present, whenever the name penicillin troches appears, the word "chewing" or "masticatory" in juxtaposition with such name.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of penicillin troches shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each troche, the quantity of each ingredient used in making the batch, the date on which the latest assay of the troches comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per troche, average moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, crystallinity and heat stability if it is crystalline penicillin, and the penicillin G content if it is crystalline penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one troche for each 5,000 troches in the batch, but in no case less than 20 troches or more than 100 troches, collected by taking single troches at such intervals throughout the entire time the troches are being made, that the quantities made during the intervals are approximately equal.

(ii) The penicillin used in making the batch; five packages, or in the case of crystalline penicillin 10 packages of each containing approximately equal portions of not less than 40 milligrams each, packaged in accordance with the requirements of § 146.24 (b).

(iii) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the service rendered with respect to each batch of penicillin troches under the regulations in this part shall be:

(1) $1.00 for each troche without masticatory substance in the sample submitted in accordance with paragraph (d) (3) (i) of this section, $2.00 for each troche with masticatory substance in such sample. $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such troches, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.31 *Penicillin dental cones (calcium penicillin dental cones, penicillin dental cones calcium salt)*—(a) *Standards of identity, strength, quality, and purity.* Penicillin dental cones are composed of calcium penicillin and one or more suitable and harmless diluents, binders, and lubricants, with or without one or both of the sulfonamides, sulfanilamide and sulfathiazole. The potency of each cone is not less than 500 units; the moisture content is not more than 1.0 percent; the content of viable microorganisms is not more than 50 per gram. If a sulfonamide is used its quantity is not less than 0.032 gram per cone. The penicillin used conforms to the requirements of § 146.24 (a) except the limitation on penicillin K content and except subparagraphs (1), (2), (4), and (7) of § 146.24 (a), but its potency is not less than 300 units per milligram. Each diluent, binder, lubricant, and sulfonamide used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each penicillin dental cone is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the cones by a plug of cotton or other like material. The composition of the immediate container, or foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of penicillin dental cones shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container;

(i) The batch mark;

(ii) The number of units in each cone of the batch;

(iii) The statement "Expiration date ____," the blank being filled in with the date which is 18 months after the month during which the batch was certified.

(2) On the outside wrapper or container:

(i) The statement "Store in refrigerator not above 15° C. (59° F.)", or "Store below 15° C. (59° F.)";

(ii) Unless it is intended solely for veterinary use and is conspicuously so labeled the statement "Cauton: To be dispensed only by or on the prescription of a ____", the blank being filled in with the words "physician" or "dentist" or

"veterinarian" or of any combination of two or all of these words, as the case may be; and

(iii) Unless the drug is intended solely for veterinary use and is so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such cones; or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure and printed matter will be sent on request.

(3) On the label and labeling if a sulfonamide is present, after the name penicillin dental cones wherever it appears, the words "with ____" in juxtaposition with such name, the blank being filled in with the name of the sulfonamide used.

(4) On the circular or other labeling within or attached to the package, if the drug is intended solely for veterinary use, directions and precautions adequate for the use of such penicillin dental cones, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

If two or more such immediate containers are in such package the number of circulars or other labeling shall not be less than the number of such containers.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of penicillin dental cones shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each cone, the quantity of each ingredient used in making the batch, the date on which the latest assay of the cones comprising such batch was completed, and that each binder, diluent, lubricant, and sulfonamide used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following made by him on an accurately representative sample of:

(i) The match; average potency per cone, average moisture, microorganism count.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one cone for each 5,000 cones in the batch; but in no case less than 20 cones or more than 100 cones, collected by taking single cones at such intervals throughout the entire time the cones are being made that the quantities made during the intervals are approximately equal;

(ii) The penicillin used in making the batch; five packages containing approximately equal portions of not less than 40 milligrams each, packaged in accordance with the requirements of § 146.24 (b);

(iii) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin dental cones under the regulations in this part shall be:

(1) $1.00 for each cone in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such cones and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.32 *Penicillin with vasoconstrictor; penicillin with ____ (the blank being filled in with the common or usual name of the vasoconstrictor).*—(a) *Standards of identity, strength, quality, and purity.* Penicillin with vasoconstrictor is a packaged combination of one immediate container of calcium penicillin and one immediate container of an aqueous solution of a vasoconstrictor. Such penicillin conforms to the standards prescribed therefor by § 146.24 except the limitation on penicillin K content, and is of such quantity that when dissolved in such solution the potency thereof is not less than 500 units per milliliter after it has been kept for seven days at a temperature of 15° C. (59° F.). Such solution contains buffering salts to produce, after the penicillin has been dissolved in it, an isotonic solution of pH 6, ±0.2, and a preservative which prevents growth of microorganisms. Each buffering salt and preservative used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* The immediate container of the penicillin and the immediate container of the aqueous solution of vasoconstrictor shall be a tight container as defined by the U. S. P. The immediate container of the penicillin shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of penicillin with vasoconstrictor shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and on the immediate container of the calcium penicillin:

(i) The batch mark;

(ii) The number of units in such container; and

(iii) The statement "Expiration date ____," the blank being filled in with the date which is 18 months after the month during which the batch was certified.

(2) On the outside wrapper or container and on the immediate container of the aqueous solution of the vasoconstrictor:

(i) A statement giving the method of dissolving the penicillin in the solution;

(ii) The potency per milliliter after the penicillin has been dissolved therein;

(iii) The statement "Store in refrigerator not above 15° C. (59° F.)," or "Store below 15° C. (59° F.)";

(iv) The statement "Warning not for injection," and unless it is intended solely for veterinary use and is conspicuously so labeled, the statement "To be administered only by a ____," the blank being filled in with the word "physician," or "dentist," or "veterinarian" or with any combination of two or all of these words as the case may be; and

(v) The conditions under which the solution should be stored, including a reference to its instability when stored under other conditions and the statement, "The solution may be kept in refrigerator for one week without significant loss of potency."

(3) On the outside wrapper or container, unless it is intended solely for veterinary use and is conspicuously so labeled:

(i) The statement "Caution: To be dispensed only by or on the prescription of a ____", the blank being filled in with the word "physician" or "dentist" or "veterinarian" or with any combination of two or all of these words, as the case may be; and

(ii) A reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of penicillin with vasoconstrictor; or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure and printed matter will be sent on request.

(4) If intended solely for veterinary use, directions and precautions adequate for the use of such penicillin with vasoconstrictor, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

If two or more such immediate containers are in such package the number of circulars or other labeling shall not be less than the number of such containers.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of penicillin for inclusion in such combination shall submit with his request a statement showing the batch mark of the penicillin, the number of packages thereof in such batch, the number of units in the immediate container thereof, and (unless it was previously submitted) the date on which the latest assay of the penicillin included in such combination was completed, the quantity of each ingredient used in making the solution of the vasoconstrictor, and a statement that such solution conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The penicillin; potency, sterility, toxicity, pyrogens, moisture, pH and clarity.

(ii) The solution after the penicillin has been dissolved therein; potency.

(3) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The penicillin; one package for each 5,000 packages in the batch, but in no case less than 20 packages or more than 100 packages, collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) In case of an initial request for certification, or when any change is made in the composition of such solution, five packages of the solution included in the combination.

(4) No result referred to in subparagraph (2) (i) of this paragraph, and no samples referred to in subparagraph (3) (i) of this paragraph, are required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin for inclusion in combination with vasoconstrictor under this part shall be:

(1) $1.00 for each immediate container submitted in accordance with paragraph (d) (3) (i) of this section, or $2.00 if no such sample is submitted; $4.00 for each package submitted in accordance with paragraph (d) (3) (ii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advanced deposit maintained in accordance with § 146.8 (d).

§ 146.33 *Penicillin for surface application*—(a) *Standards of identity, strength, quality, and purity.* Penicillin for surface application is calcium, penicillin and one or more of the diluents sodium chloride, milk sugar, sodium citrate, and dextrose. Its content of viable microorganisms is not greater than is consistent with good pharmaceutical manufacturing practice. Its moisture content is not more than 1.0 percent. The penicillin used conforms to the requirements of § 146.24 (a), except the limitation on penicillin K content and except subparagraphs (1), (2), (4) and (7) of § 146.24 (a), but its potency is not less than 300 units per milligram. Each diluent conforms to the standards prescribed therefor by the U. S. P.

(b) *Packaging.* Unless the penicillin for surface application is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each immediate container (except when its content is two or more foil or film enclosures) and each foil or film enclosure shall contain not less than 10,000 units or more than 50,000 units and shall be so sealed that the contents cannot be used without destroying such seal.

(c) *Labeling.* Each package of penicillin for surface application shall bear, on its label or labeling as hereinafter indicated, the folowing:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in the immediate container or in each foil or film enclosure therein, and the number of such foil or film enclosures;

(iii) The statement "Expiration date ____", the blank being filled in with the date which is 12 months after the month during which the batch was certified; and

(iv) In case the drug is not sterile, the statement "Not sterile—not for injection—not to be used in deep wounds or body cavities."

(2) On the outside wrapper or container;

(i) The statement "Store in refrigerator not above 15° C. (59° F.)," or "Store below 15° C. (59° F.)";

(ii) If two or more such immediate containers or foil or film enclosures are in such packages, the number of such containers or foil or film enclosures therein and the number of units in each;

(iii) Unless it is intended solely for veterinary use and is conspicuously so labeled, the statement "Caution: To be dispensed only by or on the prescription of a ____", the blank to be filled in with the word "physician" or "dentist" or "veterinarian" or with any combination of two or all of these words, as the case may be;

(iv) The conditions under which solutions of penicillin for surface application should be stored, including a reference to their instability when stored under other conditions, and the statement "The solution may be kept in refrigerator for one week without significant loss of potency"; and

(v) Unless the drug is intended solely for veterinary use and is so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of penicillin for surface application; or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure or printed matter will be sent on request.

(3) On the circular or other labeling within or attached to the package, if the drug is intended solely for veterinary use, directions and precautions adequate for the use of such penicillin for surface application including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

If two or more such immediate containers are in such package, the number of circulars or other labeling shall not be less than the number of such containers.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of penicillin for surface application shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each immediate container or foil or film enclosure, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that the sodium chloride, milk sugar, sodium citrate, and dextrose used in making such batch conform to the standards prescribed therefor by the U. S. P.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per immediate container or foil or film enclosure, moisture, microorganism count.

(ii) The penicillin used in making the batch; potency, toxicity, moisture and pH.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container or, if the drug is packed in foil or film enclosures, one such enclosure for each 5,000 such containers or enclosures in the batch, but in no case less than 20 such containers or enclosures or more than 100, collected by taking single containers or enclosures at such intervals throughout the entire time of packaging the batch, that the quantities packed during the intervals are approximately equal;

(ii) The penicillin used in making the batch; five packages containing approximately equal portions of not less than 40 milligrams each, packaged in accordance with the requirements of § 146.24 (b); and

(iii) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin for surface application under the regulations in this part shall be:

(1) $1.00 for each immediate container or foil or film enclosure, whichever is the greatest number, in the samples submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such containers or enclosures, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.34 *Tablets alum precipitated penicillin*—(a) *Standards of identity, strength, quality, and purity.* Tablets alum precipitated penicillin are tablets composed of penicillin precipitated with potassium alum, and tableted with sodium benzoate, with or without the addition of one or more suitable and harmless diluents, binders, lubricants, colorings, and flavorings. The potency of each tablet is not less than 50,000 units and if it is less than 100,000 units it is "unscored"; each tablet contains 0.3 gram of sodium benzoate; the moisture content is not more than 2.0 percent. The penicillin used conforms to the requirements of § 146.24 (a), except subparagraphs (1), (2), (4), and (7) of § 146.24 (a), but its potency is not less than 300 units per milligram. Each other substance used if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each tablet alum precipitated penicillin is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the tablets by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The number of tablets in the immediate container is such that the total number of units therein is not less than 300,000.

(c) *Labeling.* Each package of tablets alum precipitated penicillin shall bear, on its label or labeling as hereinafter indicated the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in each tablet of the batch;

(iii) The quantity of sodium benzoate in each tablet;

(iv) The statement "Expiration date ----------," the blank being filled in with the date which is 12 months after the month during which the batch was certified.

(2) On the outside wrapper or container:

(i) Unless it is intended solely for veterinary use and is conspicuously so labeled, the statement "Caution: To be dispensed only by or on the prescription of ----------," the blank being filled in with the word "physician" or "dentist" or "veterinarian" or with any combination of two or all of these words, as the case may be.

(ii) Unless it is intended solely for veterinary use and is so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such tablets alum precipitated penicillin, or a reference to a brochure, or other printed matter containing such directions and precautions, and a statement that such brochure and printed matter will be sent on request.

(3) On the circular or other labeling within or attached to the package, if it is intended solely for veterinary use, directions and precautions adequate for the use of such tablets, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

If two or more such immediate containers are in such package the number of such circulars or other labeling shall not be less than the number of such containers.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of tablets alum precipitated penicillin shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each tablet; the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per tablet, average moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, penicillin K content (unless it is crystalline penicillin G), crystallinity and heat stability if it is crystalline penicillin, and the penicillin G content if it is crystalline penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one tablet for each 5,000 tablets in the batch, but in no case less than 20 tablets or more than 100 tablets, collected by taking single tablets at such intervals throughout the entire time of tableting that the quantities tableted during the intervals are approximately equal.

(ii) The penicillin used in making the batch; six packages, or in case of crystalline penicillin 10 packages, each containing approximately equal portions of not less than 40 milligrams each, packaged in accordance with the requirements of § 146.24 (b).

(iii) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately five grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of tablets alum precipitated penicillin under this part shall be:

(1) $1.00 for each tablet in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii), of this section; and

(2) If the Commissioner considers that investigation, other than examination of such tablets and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the result for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.35 *Penicillin sulfonamide powder (calcium penicillin sulfonamide powder)*—(a) *Standards of identity, strength, quality, and purity.* Penicillin sulfonamide powder is composed of calcium penicillin and one or both of the sulfonamides, sulfanilamide and sulfathiazole. It is sterile. Its moisture content is not more than 1.0 percent. The quantity of each sulfonamide used is not more than 0.0125 gram for each 100 units of penicillin used. The penicillin used conforms to the requirements of § 146.24 (a) except limitation on penicillin K content and except subparagraphs (1), (4), and (7) of § 146.24 (a), but its potency is not less than 300 units per milligram. Each sulfonamide used conforms to the standards prescribed therefor by the U. S. P.

(b) *Packaging.* In all cases, the immediate container of penicillin sulfonamide powder shall be a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, shall be sterile at the time of filling and closing, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. If the penicillin sulfonamide powder is packaged for "dusting" purposes each package shall contain not less than 5,000 units of penicillin. If the penicillin sulfonamide powder is packaged for dental use it shall be packaged in immediate containers of colorless, transparent glass meeting the test for glass containers of type I or type II prescribed by the U. S. P. The glass containers shall be open at both ends, one of which is constricted, both ends shall be capable of closure with rubber stoppers and each such container shall contain not less than 500 units of penicillin. Each package of penicillin sulfonamide powder for dental use shall contain a suitable device for insufflation purposes.

(c) *Labeling.* Each package of penicillin sulfonamide powder shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and immediate container:

(i) The batch mark;

(ii) The number of units in each immediate container;

(iii) The statement "Expiration date _____," the blank being filled in with the date which is nine months after the month during which the batch was certified;

(iv) The statement "Store in refrigerator not above 15° C. (59° F.)," or "Store below 15° C. (59° F.)";

(v) Unless it is intended solely for veterinary use and is conspicuously so labeled, the statement "Caution: To be dispensed only by or on the prescription of a _____," the blank being filled in with the word "physician" or "dentist" or "veterinarian" or with any combination of two or all of these words, as the case may be;

(vi) Unless it is intended solely for veterinary use and is so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such penicillin sulfonamide powder or a reference to a brochure, or other printed matter containing such directions and precautions, and a statement that such brochure and printed matter will be sent on request;

(vii) On the label and the labeling, after the name penicillin sulfonamide powder wherever it appears, the words "with _____" in juxtaposition with such name, the blank being filled in with the name of the sulfonamide used.

(2) On the circular or other labeling within or attached to the package if it is intended solely for veterinary use, directions and precautions adequate for the use of such penicillin sulfonamide powder, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of penicillin sulfonamide powder shall submit with his request a statement showing the batch mark; the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each container of penicillin sulfonamide powder, the quantity of each ingredient used in making the batch, the date on which the latest assay of the penicillin sulfonamide powder comprising such batch was completed, and that such sulfonamide used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per container, average moisture, sterility.

(ii) The penicillin used in making the batch; potency, sterility, toxicity, moisture, and pH.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container of penicillin sulfonamide powder for each 5,000 containers in the batch, but in no case less than 20 such containers or more than 100. Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time the containers are being filled that the quantities made during the intervals are approximately equal.

(ii) The penicillin used in making the batch; five packages containing approximately equal portions of not less than 40 milligrams each, packaged in accordance with the requirements of § 146.24 (b).

(iii) In case of an initial request for certification, each sulfonamide used in making the batch; one package of each containing approximately five grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin sulfonamide powder under the regulations in this part shall be:

(1) $2.00 for each immediate container of penicillin sulfonamide powder in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such penicillin sulfonamide powder and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee if covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.36. *Penicillin vaginal suppositories (sodium penicillin vaginal suppositories, calcium penicillin vaginal suppositories, potassium penicillin vaginal suppositories, penicillin vaginal suppositories sodium salt, penicillin vaginal suppositories calcium salt, penicillin vaginal suppositories potassium salt)*—(a) *Standards of identity, strength, quality, and purity.* Penicillin suppositories are suppositories composed of penicillin in a base of spermaceti and cocoa butter. The potency of each suppository is not less than 100,000 units; its moisture content is not more than 1.0 percent; its content of viable microorganisms is not more than 50 per gram. The penicillin used conforms to the requirements of § 146.24 (a), except subparagraphs (1), (2), (4), and (7) of § 146.24 (a), but its potency is not less than 300 units per milligram. The spermaceti and cocoa butter conform to the standards prescribed therefor by the U. S. P.

(b) *Packaging.* In all cases, the immediate container of penicillin vaginal suppositories shall be a tight container

as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of penicillin vaginal suppositories shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in each suppository of the batch; and

(iii) The statement, "Expiration date ----------", the blank being filled in with the date which is 12 months after the month during which the batch was certified.

(2) On the outside wrapper or container:

(i) The statement "Store in refrigerator not above 15° C. (59° F.)", or "Store below 15° C. (59° F.)";

(ii) Unless it is intended solely for veterinary use and is conspicuously so labeled, the statement "Caution: To be dispensed only by or on the prescription of a ----------", the blank being filled in with the word "physician" or "veterinarian" or both as the case may be; and

(iii) Unless the drug is intended solely for veterinary use and is so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such suppositories; or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure or printed matter will be sent on request.

(3) On the circular or other labeling within or attached to the package, if the drug is intended solely for veterinary use, directions and precautions adequate for the use of such suppositories, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of penicillin vaginal suppositories shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each suppository, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that the spermaceti and cocoa butter used in making such batch conform to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of;

(i) The batch; average potency per suppository, moisture, microorganism count.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, penicillin K content (unless it is crystalline penicillin G), crystallinity and heat stability if it is crystalline penicillin, and the penicillin G content if it is crystalline penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph such person shall submit in connection with his request in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one suppository for each 5,000 suppositories in the batch, but in no case less than 20 suppositories or more than 100 suppositories, collected by taking single suppositories at such intervals throughout the entire time the suppositories are being made, that the quantities made during the intervals are approximately equal.

(ii) The penicillin used in making the batch; six packages, or in the case of crystalline penicillin 10 packages, each containing approximately equal portions of not less than 40 milligrams each, packaged in accordance with the requirements of § 146.24 (b).

(iii) In case of an initial request for certification, the spermaceti and cocoa butter used in making the batch; one package of each containing respectively approximately 10 grams and 100 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin vaginal suppositories under the regulations in this part shall be:

(1) $2.00 for each suppository in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d). (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations other than examination of such suppositories and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.37 *Buffered crystalline penicillin.* Buffered crystalline penicillin conforms to all requirements prescribed by § 146.24 for crystalline penicillin, and is subject to all procedures prescribed by § 146.24 for crystalline penicillin, except that:

(a) It contains the buffer sodium citrate in a quantity not less than 4.0 percent and not more than 5.0 percent by weight of its total solids; such sodium citrate conforms to the standards prescribed therefor by the U. S. P.;

(b) If it is crystalline penicillin G the potency in units per milligram is corrected for the sodium citrate content;

(c) The circular or other labeling within or attached to the package, if it is packaged for dispensing, shall bear, in lieu of the statement prescribed for crystalline penicillin by § 146.24 (c) (3) (iii), the statement "Sterile solution may be kept in refrigerator for one week without significant loss of potency";

(d) A person who requests certification of a batch shall submit with his request a statement showing the quantity of sodium citrate used in making the batch, that such sodium citrate conforms to the requirements prescribed therefor by this section, and in case of an initial request for certification he shall submit an accurately representative sample of such sodium citrate consisting of approximately 5 grams; and

(e) The fee for the services rendered with respect to the sample of sodium citrate submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146.38 *Capsules buffered penicillin with pectin hydrolysate. (Capsules buffered potassium penicillin with pectin hydrolysate)*—(a) *Standards of identity, strength, quality and purity.* Capsules buffered penicillin with pectin hydrolysate are capsules composed of potassium penicillin with pectin hydrolysate and sodium citrate enclosed in a hard gelatin capsule. The potassium penicillin with pectin hydrolysate is prepared with lyophylizing a solution containing one part potassium penicillin and three parts of pectin hydrolysate by weight. The potency of each capsule is not less than 50,000 units. Its moisture content is not more than 4.0 percent. The penicillin used conforms to the requirements prescribed by § 146.24 (a) for potassium penicillin except subparagraphs (2), (4), and (7) of § 146.24 (a). The pectin hydrolysate is obtained by mild hydrolysis of pectin with sodium hydroxide and hydrochloric acid. It is a free flowing and opalescent solution light tan to beige in color and is precipitated by the lower alcohols and ketones. Its pH is 6.0 to 7.0. It is substantially free of any turbidity or undissolved material. The pectin used conforms to the standards prescribed by the N. F. The sodium citrate; and the sodium hydroxide and hydrochloric acid used in the preparation of the pectin hydrolysate conform to the standards prescribed therefor by the U. S. P.

(b) *Packaging.* Unless each capsule of buffered penicillin with pectin hydrolysate is enclosed in foil or plastic film and such enclosure complies with the definition of a tight container as prescribed by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The

immediate container may also contain a desiccant separated from the capsules by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The number of capsules in the immediate container is such that the total number of units therein is not less than 300,000.

(c) *Labeling.* Each package of capsules buffered penicillin with pectin hydrolysate shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in each capsule of the batch;

(iii) The quantity of the sodium citrate in each capsule of the batch; and

(iv) The statement "Expiration date _____," the blank being filled in with the date which is twelve months after the month during which the batch was certified.

(2) On the outside wrapper or container:

(i) Unless it is intended solely for veterinary use and is conspicuously so labeled, the statement "Caution: To be dispensed only by or on the prescription of a _____", the blank being filled in with the word "physician" or "dentist" or "veterinarian" or any combination of two or all of these words, as the case may be.

(ii) Unless it is intended solely for veterinary use and is so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such capsules, or a reference to a brochure, or other printed matter containing such directions and precautions, and a statement that such brochure or printed matter will be sent on request.

(3) On the circular or other labeling within or attached to the package, if it is intended solely for veterinary use, directions and precautions adequate for the use of such capsules, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

If two or more such immediate containers are in such package the number of such circulars or other labeling shall not be less than the number of such containers.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of capsules buffered penicillin with pectin hydrolysate shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each capsule, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per capsule, average moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, penicillin K content (unless it is crystalline penicillin G), crystallinity, and heat stability, and if it is crystalline penicillin G, penicillin G content.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one capsule for each 5,000 capsules in the batch, but in no case less than 20 capsules or more than 100 capsules, collected by taking single capsules at such intervals throughout the entire time of capsuling that the quantities capsuled during the intervals are approximately equal.

(ii) The penicillin used in making the batch; ten packages containing approximately equal portions of not less than 40 milligrams each, packaged in accordance with the requirements of § 146.24 (b).

(iii) In case of an initial request for certification, one package of approximately 250 cc of the pectin hydrolysate and one package of approximately five grams of the sodium citrate used in making the batch, one package of approximately 50 cc of the hydrochloric acid and one package of approximately five grams of the sodium hydroxide used in preparing the pectin hydrolysate.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or such sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of capsules buffered penicillin with pectin hydrolysate under the regulations in this part shall be:

(1) $1.50 for each capsule in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the sample submitted in accordance with paragraph (d) (3) (ii) and (iii), of this section; and

(2) If the Commissioner considers that investigations, other than examination of such capsules and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

NOTE: Sections 146.99 to 146.100, inclusive, reserved for future provisions.

§ 146.101 *Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride (streptomycin calcium chloride complex)*—(a) *Standards of identity, strength, quality, and purity.* Streptomycin sulfate is the sulfate salt of a kind of streptomycin or a mixture of two or more such salts; streptomycin hydrochloride is the hydrochloride salt of a kind of streptomycin or a mixture of two or more such salts; streptomycin phosphate is the phosphate salt of a kind of streptomycin or a mixture of two or more such salts; streptomycin trihydrochloride calcium chloride is the double salt of a kind of streptomycin or a mixture of two or more such salts. Each such drug is so purified and dried that:

(1) Its potency is not less than 300 micrograms per milligram;

(2) It is sterile;

(3) It is nontoxic;

(4) It is nonpyrogenic;

(5) It contains no histamine or histamine-like substances;

(6) Its moisture content is not more than 3.0 percent;

(7) Its pH in aqueous solution of 0.2 gram per milliliter is not less than 4.5 and not more than 7.0;

(8) Its solution in water for injection U. S. P., dextrose injection 5.0 percent U. S. P., or physiological salt solution U. S. P., prepared by adding 0.2 gram (estimated) of streptomycin per milliliter, is of such clarity that it is substantially free of any turbidity or undissolved material.

(b) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing it shall be in immediate containers of colorless transparent glass which meet the test for glass containers of type I or type II prescribed by the U. S. P., closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness; each such container shall contain 0.5 gram, 1.0 gram, 2.0 gram, 3.0 gram, 4.0 gram, or 5.0 gram, and each may be packaged in combination with a container of the solvent, water for injection U. S. P., dextrose injection 5 percent U. S. P., or physiological salt solution U. S. P.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of grams in the immediate container;

(iii) The statement "Expiration date _____", the blank being filled in with the date which is 12 months after the month during which the batch was certified; and

(iv) The statement "For Manufacturing Use", "For Repacking", or "For Manufacturing Use or Repacking" when packaged for repacking or for use as an ingredient in the manufacture of another drug, as the case may be.

(2) On the circular or other labeling within or attached to the package, if it is packaged for dispensing, adequate directions for use and warnings as required by section 502 (f) of the act, including:

(i) Clinical indications;

(ii) Dosage and administration, including method of preparation and strength of solutions for different routes of injection and local application;

(iii) The conditions under which such solutions should be stored including the statement "Sterile solution may be stored at room temperature for one week without significant loss of potency";

(iv) Contraindications; and

(v) Untoward effects that may accompany administration, including sensitization.

If two or more immediate containers are in such package, the number of such circulars or other labeling shall not be less than the number of such containers.

(d) *Requests for certification, check tests, and assays; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of grams in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, sterility, toxicity, pyrogens, histamine content, moisture, pH, and clarity. If such batch or any part thereof is to be packaged with a solvent such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) If such batch is packaged for dispensing, such person shall submit with his request a sample consisting of one immediate container for each 5,000 immediate containers in such batch, but in no case shall such sample consist of less than 5 or more than 12 immediate containers.

Such sample shall be collected by taking single immediate containers, before and after labeling, at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(3) If such batch is packaged for repacking or for use as an ingredient in the manufacture of another drug, such person shall submit with his request a sample containing five approximately equal portions of at least 0.5 gram each taken from different parts of such batch; each such portion shall be packaged in a separate container, and in accordance with the requirements of paragraph (b) of this section.

(4) In connection with contemplated requests for certification of repackaged batches or batches of another drug in the manufacture of which it is to be used, the manufacturer of a batch which is to be so repacked or used may request the Commissioner to make check tests and assays on a sample of such batch taken as prescribed by subparagraph (3) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $15.00 for each immediate container in the sample submitted in accordance with paragraphs (d) (2), (3), and (4) of this section.

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

This order, which provides for the certification of a new penicillin product, capsules buffered penicillin with pectin hydrolysate, and which includes a revision of all of the existing regulations for certification of penicillin-containing drugs heretofore promulgated and published in this part, and which also provides for certification of streptomycin-containing drugs, shall become effective upon publication in the FEDERAL REGISTER since both the public and the affected industries will benefit by the earliest effective date, and I so find.

Notice and public procedure are not necessary prerequisites to the promulgation of this order and would be contrary to the public interest, and I so find, since it was drawn in collaboration with interested members of the affected industries and since it would be against public interest to delay the marketing of these drug products.

Dated: April 1, 1947.

[SEAL] WATSON B. MILLER,
Administrator.

[F. R. Doc. 47-3236; Filed, Apr. 3, 1947; 9:36 a. m.]

PART 170—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL TEA ACT

TEA STANDARDS

Correction

In Federal Register Document No. 47-2803, appearing on page 1979 of the issue for Wednesday, March 26, 1947, paragraph (b) (3) of § 170.19 should read as follows:

(3) India (to be used for all fully fermented East India type teas).

TITLE 24—HOUSING CREDIT

Chapter VIII—Office of Housing Expediter

[Housing Expediter Priorities Order 6]

PART 801—PRIORITIES ORDERS UNDER VETERANS' EMERGENCY HOUSING ACT OF 1946

OFFICIAL SIGNATURE FOR OFFICE OF HOUSING EXPEDITER

§ 801.6 *Official signature for Office of Housing Expediter.* (a) The Housing Expediter may take in his own name any action in performance of the functions vested in him under the Veterans' Emergency Housing Act of 1946 and Executive Order 9836.

Except as otherwise provided in this section, all actions in performance of the functions vested in the Housing Expediter under the Veterans' Emergency Housing Act of 1946 and Executive Order 9836 (but not including delegations of authority) shall be taken and issued in the name of the Office of the Housing Expediter, countersigned or attested by the Authorizing Officer in substantially the following form:

Office of the Housing Expediter
By _____
Authorizing Officer

This shall be the official signature of the Office of the Housing Expediter.

Unless authorized by the Housing Expediter to take official action in his own name, every officer and employee of the Office of the Housing Expediter shall be governed by the provisions of this section in taking action requiring the official signature of the Office of the Housing Expediter.

(b) Appointment of Authorizing Officer: James V. Sarcone is hereby appointed Authorizing Officer for the Office of the Housing Expediter. The Authorizing Officer will be governed by instructions of the Housing Expediter or his duly authorized representative in counter-signing, attesting, or issuing any action of the Office of the Housing Expediter.

(c) Effective date: This section shall become effective April 1, 1947. (60 Stat. 207)

FRANK R. CREEDON,
Housing Expediter.

[F. R. Doc. 47-3235; Filed, Apr. 3, 1947; 8:48 a. m.]

TITLE 31—MONEY AND FINANCE: TREASURY

Chapter I—Monetary Offices, Department of the Treasury

PART 131—GENERAL LICENSES UNDER EXECUTIVE ORDER 8389, APRIL 10, 1940, AS AMENDED, AND REGULATIONS ISSUED PURSUANT THERETO

EXEMPTION OF TRANSACTIONS WITH RESPECT TO CERTAIN CURRENCIES AND SECURITIES

APRIL 4, 1947.

Amendment to General License No. 87 under Executive Order No. 8389, as amended, Executive Order No. 9193, as amended, section 5 (b) of the Trading With the Enemy Act, as amended by the First War Powers Act, 1941, relating to foreign funds control.

Section 131.87 (General License No. 87) is hereby amended to read as follows:

§ 131.87 *Exemptions from section 2A (2) of the order and from General Ruling No. 5—(a) Transactions exempted from section 2A (2) of the order.* A general license is hereby granted exempting all transactions from the provisions of section 2A (2) of the order, except transactions with respect to any securities of evidences thereof which, whether in registered or bearer form, are transferable or assignable and which either;

(1) Were issued or guaranteed prior to December 7, 1941, by the United States or any state, territory, district, possession, or other political subdivision, agency or instrumentality of or in the United States or by any partnership, association, corporation or other organization organized or having its principal place of business in the United States; or

(2) Were issued prior to December 7, 1941, and are payable in the United States exclusively or alternatively in United States dollars, regardless of the nature or location of the issuer: *Provided,* That this exception shall not be deemed to preclude transactions with respect to securities or evidences thereof which are physically situated in Great Britain, Canada, Newfoundland, or Bermuda, or to which Form TFEL–2 has been attached, or with respect to which a certification under paragraph (1) of § 131.95 (General License No. 95) has been issued.

(b) *Exemption of currency and certain securities from General Ruling No. 5.* The following currency and securities are hereby exempted from the provisions of General Ruling No. 5:

(1) All currency; and

(2) All securities other than those to which the exception of paragraph (a) of this section applies. (Sec. 5 (b), 40 Stat. 415, 966; sec. 2, 48 Stat. 1; 54 Stat. 179; sec. 301, 55 Stat. 839; 12 U. S. C. 95a; 50 U. S. C. App. Sup., 5 (b); E. O. 8389, April 10, 1940, as amended by E. O. 8785, June 14, 1941, E. O. 8832, July 26, 1941, E. O. 8963, Dec. 9, 1941, and E. O. 8998, Dec. 26, 1941, E. O. 9193, July 6, 1942, as amended by E. O. 9567, June 8, 1945; 3 CFR, Cum. Supp., 10 F. R. 6917; Regulations, Apr. 10, 1940, as amended June 14, 1941, Feb. 19, 1946, June 28, 1946 and Jan. 1, 1947; 31 CFR, Cum. Supp., 130.1–7, 11 F. R. 1769, 7184, 12 F. R. 6)

[SEAL] JOHN W. SNYDER,
Secretary of the Treasury.

[F. R. Doc. 47-3174; Filed, Apr. 3, 1947; 8:47 a. m.]

APPENDIX A TO PART 131—GENERAL RULINGS UNDER EXECUTIVE ORDER NO. 8389, APRIL 10, 1940, AS AMENDED, AND REGULATIONS ISSUED PURSUANT THERETO

EXEMPTION OF CURRENCY AND CERTAIN SECURITIES FROM GENERAL RULING 5

CROSS REFERENCE: For exemption of currency and certain securities from General Ruling 5, see § 131.87, *supra.*

TITLE 32—NATIONAL DEFENSE

Chapter XXIII—War Assets Administration

[Reg. 1]

PART 8301—DESIGNATION OF DISPOSAL AGENCIES AND PROCEDURES FOR REPORTING SURPLUS PROPERTY LOCATED WITHIN THE CONTINENTAL UNITED STATES, ITS TERRITORIES AND POSSESSIONS

War Assets Administration Regulation 1, January 29, 1947, entitled "Designation of Disposal Agencies and Procedures for Reporting Surplus Property Located within the Continental United States, Its Territories and Possessions" (12 F. R. 863), is hereby revised and amended as herein set forth. New matter is indicated by underscoring. Order 1, July 19, 1946,[1] as amended (11 F. R. 7973; 12 F. R. 100, Order 2, March 7, 1947 (12 F. R. 1838), Order 3, June 13, 1946, as amended (11 F. R. 6774, 9572, 14490), Order 7, July 19, 1946 (11 F. R. 7977), Order 8, August 16, 1946 (11 F. R. 9760), Order 9, May 14, 1946 (11 F. R. 5399), Order 11, November 30, 1946 (11 F. R. 14074), under this part shall remain in full force and effect.

Sec.
8301.1 Definitions.
8301.2 Designation of disposal agencies; continental United States.
8301.3 Designation of disposal agencies; territories and possessions.
8301.4 Designation of disposal agency for, and disposal of, military property.
8301.5 Use of Standard Commodity Classification for purpose of assignments.
8301.6 Declaration of surplus property.
8301.7 Declarations of surplus personal property; forms; description of property.
8301.8 Declarations of surplus personal property; special information from owning agencies.
8301.9 Declaration of surplus real property.
8301.10 Continental United States; filing declarations of surplus personal property resulting from contractor inventories.
8301.11 Continental United States; filing declarations of surplus personal property.
8301.12 Continental United States, territories and possessions; declarations of surplus real property.
8301.13 Territories and possessions; filing declarations of surplus personal property.
8301.14 Forwarding declarations of surplus; notice.
8301.15 Withdrawals.
8301.16 Sales by a disposal agency other than the one to which the property is assigned.
8301.17 Transfer of surplus property between territories and possessions and continental United States.
8301.18 Authority of disposal agencies to dispose of surplus property.
8301.19 Regulations to be reported to the War Assets Administrator.
8301.20 Records and reports.

AUTHORITY: §§ 8301.1 to 8301.20, inclusive, issued under the Surplus Property Act of 1944 as amended (58 Stat. 765, as amended; 50 U. S. C. App. Sup. 1611); Pub. Law 181, 79th Cong. (59 Stat. 533; 50 U. S. C. App. Sup. 1614a, 1614b); and E. O. 9689 (11 F. R. 1265).

§ 8301.1 *Definitions—(a) Terms defined in act.* Terms not defined in paragraph (b) of this section which are defined in the Surplus Property Act of 1944 shall in this part have the meaning given to them in the act.

(b) *Other terms.* (1) "Continental United States" means the 48 States and the District of Columbia.

(2) "Territories and possessions" means Hawaii, Alaska (including the Aleutian Islands), Puerto Rico, and the Virgin Islands.

(3) "Real property" means all classes of real property together with any fixtures and improvements thereon and is not limited to the definition thereof as contained in section 23 of the act.

(4) "Section 23 real property" means property consisting of land, together with any fixtures and improvements thereon (including hotels, apartment houses, hospitals, office buildings, stores, and other commercial structures) located outside the District of Columbia, but does not include (i) commercial structures constructed by, at the direction of, or on behalf of any Government agency, (ii) commercial structures which the Administrator determines have been made an integral part of a functional or economic unit which should be disposed of as a whole, and (iii) war housing, industrial plants, factories, airports, airport facilities, or similar structures and facilities, or the sites thereof, or land which the Administrator determines essential to the use of any of the foregoing.

(5) "Handbook of Standards" means the Handbook of Standards for describing Surplus Property prepared for the Surplus War Property Administration by the War Production Board (U. S. Government Printing Office).

(6) "Standard Commodity Classification" means the Standard Classified List of Commodities, being Volume I of the Standard Commodity Classification, May, 1943 (U. S. Government Printing Office).

§ 8301.2 *Designation of disposal agencies; continental United States.* The

[1] Reg. 1, Order 1, July 19, 1946 to remain in effect until issuance of revision effective as of April 5, 1947.

following Government agencies are hereby designated as disposal agencies for surplus property located within the continental United States: *Provided*, That the Administrator may assign any real property to any of the disposal agencies designated in this part regardless of its classification whenever the Administrator shall determine such assignment appropriate to facilitate disposal:

(a) *Patrol vessels; Navy Department.* The Navy Department is hereby designated as the disposal agency for certain patrol vessels assigned to it by Order 1 under this part.

(b) *Ships and maritime personal property: Maritime Commission and War Assets Administration.* (1) (i) The United States Maritime Commission, pursuant to the provisions of section 10 (b) of the Surplus Property Act of 1944, is the disposal agency for surplus vessels which it determines to be merchant vessels or capable of conversion to merchant use which shall be disposed of under the Merchant Marine Act of 1936 [2] as amended, and other laws authorizing the sale of such vessels, and not under the Surplus Property Act of 1944 or regulations thereunder. Such vessels as determined by the United States Maritime Commission consist of: "all non-combatant vessels, except landing craft of all types, landing ship tanks, undocumented vessels under thirty (30) feet in length without propulsion machinery, and life boats with or without propulsion machinery, when located within the continental United States."

(ii) The United States Maritime Commission may from time to time determine that other vessels or types of vessels are not merchant vessels or capable of conversion to merchant use. In such cases specific notice of such vessels or types of vessels shall be immediately reported to the War Assets Administration upon the making of the determination.

(2) The United States Maritime Commission is hereby designated as disposal agency for the disposal of the following types of surplus vessels located in the continental United States which have been determined by the Commission not to be merchant vessels or capable of conversion to merchant use: "landing craft of all types, including landing ship tanks" together with any additional vessels determined later not to be merchant vessels or capable of conversion to merchant use, as provided in subparagraph (1) (ii) supra.

(3) The War Assets Administration is hereby designated as disposal agency for all marine personal property (except as otherwise provided in this section), including undocumented vessels which are under thirty (30) feet in length and without propulsion machinery, and including life boats with or without propulsion machinery, and other items assigned to War Assets Administration by Order 1 [1] under this part.

(c) *Agricultural commodities and food; Department of Agriculture.* The Department of Agriculture is hereby designated as the disposal agency for agricultural commodities and food. This general class of property, "agricultural commodities and food" includes property assigned to the Department of Agriculture by Order 1 under this part.

(d) *Agricultural, forest, grazing and mineral property; Department of Agriculture.* The Department of Agriculture is hereby designated as the disposal agency for surplus section 23 real property located within the continental United States which the Administrator shall classify as agricultural, forest, grazing, or mineral property: *Provided, however*, That the Department of Interior is designated as disposal agency for all such property classified as grazing or mineral property which was assigned to it for disposal prior to the 23d day of February 1947.

(e) *All other property: War Assets Administration.* The War Assets Administration is hereby designated as disposal agency for all real and personal property of every type and classification located in the continental United States, declared surplus by owning agencies, except those types assigned to other disposal agencies under subparagraph (b) (2) and paragraphs (c) and (d) of this section: *Provided*, That:

(1) The Federal Works Agency is designated as disposal agency for all section 23 real property which was assigned to it for disposal prior to the 29th day of January 1947; and

(2) The National Housing Agency is designated as disposal agency for all residential and other property which was assigned to it for disposal prior to the 29th day of January 1947.

§ 8301.3 *Designation of disposal agencies; territories and possessions.* The following designations of Government agencies as disposal agencies for surplus property located in the territories and possessions of the United States as defined in § 8301.1, are hereby made, *Provided*, That the Administrator may assign any real property located in the territories and possessions to any of the disposal agencies designated in this part regardless of its classification whenever the Administrator shall determine such assignment appropriate to facilitate disposal.

(a) *All personal property not otherwise assigned; War Assets Administration.* War Assets Administration is hereby designated as the disposal agency for all personal property, including aircraft and property peculiar to aircraft, not otherwise assigned under this section and located in the territories and possessions.

(b) *Ships: Maritime Commission.* The United States Maritime Commission, pursuant to the provisions of section 10 (b) of the Surplus Property Act of 1944, is the disposal agency for surplus vessels which it determines to be merchant vessels or capable of conversion to merchant use, to be disposed of under the Merchant Marine Act of 1936 as amended, and other laws authorizing the sale of such vessels, and not under the Surplus Property Act of 1944 or regulations thereunder. Such vessels as determined by the United States Maritime Commission consist of: "all non-combatant vessels of 1,500 gross tons or over, except LST's, located in the territories and possessions.

(c) *All real property; Department of the Interior.* The Department of the Interior is hereby designated as the disposal agency for all real property located in the territories and possessions.

§ 8301.4 *Designation of disposal agency for, and disposal of, military property.* The Department of State is hereby designated as the disposal agency for surplus military property located in the continental United States, its territories and possessions, for disposal to other governments. With the consent of the State Department, owning agencies are authorized to file declarations of such surplus property with the Department of State, Office of the Foreign Liquidation Commissioner, Washington 25, D. C.; such declarations of surplus as are filed with the State Department shall have endorsed thereon the approval of an officer of the owning agency to be designated as its representative for coordination with the State Department. If there are included in such declarations of surplus any substantial quantity of items which may be used for civilian purposes, the State Department shall consult with the appropriate Government agencies (including domestic disposal agencies) to ascertain whether such items are required for reserves established under the act for priority or preference claimants or are urgently required for the domestic economy. If the Department of State determines that such items are so required, it shall forward the declaration of surplus covering such items to the appropriate disposal agency. The term "military property" includes all arms, ammunition, spare parts, accessories, maintenance and service tools and equipment, cleaning and preserving materials, military automotive equipment, aircraft and aircraft maintenance and servicing equipment, naval combat type and auxiliary vessels (excluding vessels referred to in section 3 (d) of the act), special military clothing and equipage, and all other items required to train, equip, and maintain military, aviation, and naval units as listed in approved tables of organization and equipment and technical publications pertaining thereto for United States armed forces, and production equipment specially de-

[1] Reg. 1, Order 1, July 19, 1946 to remain in effect until issuance of revision effective as of April 5, 1947.

[2] 49 Stat. 1985; 46 U. S. C. 1101–1279.

signed to produce munitions. No disposal agency other than the State Department shall dispose of any arms, ammunition, and implements of war as defined by the President's Proclamation No. 2549 of April 9, 1942, and facilities intended for the production thereof to any foreign government without the consent in writing of the State Department.

§ 8301.5 *Use of Standard Commodity Classification for purpose of assignments.* The assignments made in Order 1 under this part through the use of Standard Commodity Classification code numbers are intended to be in aid of and supplementary to the assignments of the general classes of property made in § 8301.2. If, therefore, items fall within a general class of property assigned by this part but these items are not listed in the Standard Commodity Classification, they shall be disposed of by the disposal agency to which the general class of property is assigned. Similarly, if the Standard Commodity Classification does not indicate that an item is included within more than one of the general classes of property assigned in § 8301.2, the assignment of the general class shall control.

§ 8301.6 *Declaration of surplus property.* Each owning agency shall, pursuant to section 11 (a) of the act, continuously survey property in its control and determine that which is surplus to its needs and responsibilities, and, except for such property as the owning agency itself is authorized to dispose of, it shall report such surplus property to the Administrator and to the appropriate disposal agency designated in this part. The reporting of surplus personal property by an owning agency to a disposal agency shall constitute a declaration of surplus. When the disposal agency has notified the owning agency of the date on which any specific location will be organized for disposal operations at the site, the owning agency shall discontinue, as of the specified date, all declarations on WAA Form 1001 (formerly Form SPB-1) of property at such location, unless expressly requested otherwise by the disposal agency.

§ 8301.7 *Declarations of surplus personal property; forms; description of property.* Subject to the provisions of § 8301.9 owning agencies shall declare surplus personal property to the Administrator and to the appropriate disposal agencies on forms as prescribed by Order 3 under this part. The property shall be described in sufficient detail to furnish the disposal agency with an adequate basis for disposal. Unless other provision is made, the minimum standards of descripiton prescribed by the Handbook of Standards for Describing Surplus Property shall be used as a guide for all such descriptions.

§ 8301.8 *Declarations of surplus personal property; special information from owning agencies*—(a) *Limitations on power of disposal.* Declarations of surplus personal property shall fully set forth any legal restrictions upon the authority of the Government to dispose of any personal property, including any restrictions upon the disposal or use thereof arising from any patents or any contract relating thereto, unless such information relating to patents has otherwise been furnished to the disposal agencies.

(b) *Red Cross property.* Declarations of surplus personal property shall designate any such property known to have been processed, produced or donated by the American Red Cross.

§ 8301.9 *Declaration of surplus real property.* The owning agency shall notify the Administrator by a letter of intent on the date upon which it is determined that real property and any personal property connected therewith is no longer required by the owning agency. Where surplus personal property is located in or on such real property, the owning agency shall, unless otherwise directed by the Administrator, declare such personal property surplus in conjunction with the real property. The filing with the Administrator of an acceptable WAA Form 1005, together with WAA Form 1001 where personal property is involved, shall constitute a declaration of surplus real property.

§ 8301.10 *Continental United States; filing declarations of surplus personal property resulting from contractor inventories.* If an owning agency takes possession of any contractor inventory located in the continental United States, it may declare such property surplus to the regional office of the War Assets Administration for the region wherein the property is located. If any property so declared is of a class other than that which is assigned to the War Assets Administration by this part, it will make the necessary classification and forward the declarations to the appropriate disposal agencies unless disposal of such property by the War Assets Administration is authorized under § 8301.16. This section shall not apply to agricultural commodities and foods.

§ 8301.11 *Continental United States; filing declarations of surplus personal property.* Declarations of surplus personal property located within the continental United States shall be filed on forms prescribed by Order 3 under this part at the office of the War Assets Administrator, Washington 25, D. C., and at the office of the appropriate disposal agencies as follows except as otherwise indicated in Order 2 under this part: At the regional offices of the War Assets Administration and at the Washington, D. C. offices of all other disposal agencies. The locations of these offices and the areas comprised by the regions are set forth in § 8301.52[3] under this part.

§ 8301.12 *Continental United States, territories and possessions; declarations of surplus real property*—(a) *Filing.* Declarations of surplus real property shall be filed with the War Assets Administrator, Washington 25, D. C. Where personal property is to be declared surplus in conjunction with real property, the owning agency shall in advance notify the appropriate regional office of War Assets Administration or, in the territories and possessions, the appropriate office of the Department of the Interior, of the date on which WAA Form 1001 will be ready for filing. Such office may designate a representative with whom the form may be filed at the installation site and who shall be authorized to accept the declaration for filing. If for any reason such form is not so filed with the designated representative it shall be filed at the War Assets Administration regional office, or, in the territories and possessions, at the appropriate office of the Department of the Interior.

(b) *Transmitting.* The Administrator will transmit the declaration to the appropriate disposal agency and will notify the owning agency of such transmittal.

§ 8301.13 *Territories and possessions; filing declarations of surplus personal property.* Declarations of surplus personal property located in the territories and possessions shall be filed on the forms prescribed in Order 3 under this part with the War Assets Administrator, Washington 25, D. C., and at such offices of the appropriate disposal agency as are specified in Order 2 under this part, or, if not specified, as the disposal agency may direct.

§ 8301.14 *Forwarding declarations of surplus; notice.* Whenever surplus declarations are forwarded by one disposal agency to another disposal agency or to the Administrator under this part, the forwarding disposal agency shall so notify the owning agency which filed the declaration.

§ 8301.15 *Withdrawals*—(a) *Personal property.* With the consent of the disposal agency, an owning agency may withdraw personal property which it has declared surplus and for which a declaration has been transmitted to such disposal agency pursuant to this part: *Provided, however,* That such withdrawals may be made only (1) on the forms prescribed by Order 3 under this part, (2) by the technical service, bureau, or other constituent part of the owning agency, which made the declaration, or its successor, and (3) upon the agreement of the owning agency to pay all freight charges in connection with the movement of the property to the point designated by such agency, in cases where the disposal agency has assumed custody and accountability.

(b) *Real property.* A request by an owning agency for the withdrawal of a declaration of surplus real property shall be transmitted to the Administrator by the filing of WAA Form 1005[4] (formerly Form SPB-5) with complete justification for the requested withdrawal. In cases where the disposal agency has incurred direct costs or obligations in connection with the care or handling of the property, the withdrawal by the owning agency shall be on condition that the disposal agency be reimbursed for any direct costs so incurred and relieved of any such obligations. The Administrator, after consideration of the request and any additional evidence which he deems appropriate, will notify the owning agency and

[3] Reg. 1, Order 2 (12 F. R. 1833).

[4] Reg. 1, Order 3 (11 F. R. 6774, 9572, 14490).

the appropriate disposal agency, if the declaration previously was transmitted thereto, of his decision.

§ 8301.16 *Sales by a disposal agency other than the one to which the property is assigned.* A disposal agency may dispose of personal property which is declared to it as surplus but which is assigned under this part to another disposal agency: *Provided, however,* That disposal of any item of personal property in excess of a reported cost of three hundred dollars ($300) may be made only with the consent of such other disposal agency.

§ 8301.17 *Transfer of surplus property between territories and possessions and continental United States.* No surplus personal property shall be transferred by a disposal agency from one territory or possession to another, or to the continental United States, without the consent of the disposal agency acting as such at the place of destination. Where such consent is given and the transfer is made, disposal shall be made by the disposal agency acting as such at the place of destination.

§ 8301.18 *Authority of disposal agencies to dispose of surplus property*—(a) *In general.* The disposal agencies designated in this part are hereby authorized and directed to dispose of property declared or assigned to them as surplus. Disposals shall be made in accordance with regulations, orders, and instructions of the War Assets Administrator and those of the Surplus Property Administrator, the Surplus Property Board and the Surplus War Property Administration (created by Executive Order 9425, February 19, 1944) which have not been rescinded and superseded, and in accordance with the objectives and provisions of the act.

(b) *Aircraft, aircraft parts, radio and electrical equipment.* The appropriate disposal agencies are hereby authorized, in accordance with section 19 (c) of the act, to dispose of aircraft and aircraft parts and radio and electrical equipment.

(c) *Small business.* The Department of Commerce, having been vested by Executive Order 9665 (11 F. R. 3) with the functions and responsibilities of Smaller War Plants Corporation set forth in sections 18 (c) and (d) of the Surplus Property Act of 1944, should bring to the attention of the War Assets Administrator, the disposal agencies, and the Reconstruction Finance Corporation the needs and requirements of small business, and any cases or situations which have resulted in or would effect discriminations against such business; and the Reconstruction Finance Corporation, in the exercise of its authority to purchase surplus property for resale to such business, and disposal agencies shall give consideration to the needs and requirements of small business as reported to them by the Department of Commerce so as to prevent any discrimination against small business in the disposals of surplus property.

§ 8301.19 *Regulations to be reported to the War Assets Administrator.* Each owning agency and each disposal agency shall file with the War Assets Administrator copies of all regulations, orders, and instructions of general applicability which it may issue in furtherance of the provisions, or any of them, of this part.

§ 8301.20 *Records and reports.* Owning and disposal agencies shall prepare and maintain such records as will show full compliance with the provisions of this part and with the applicable provisions of the act. Reports shall be prepared and filed with the War Assets Administrator in such manner as may be specified by order issued under this part subject to the approval of the Bureau of the Budget pursuant to the Federal Reports Act of 1942.

This revision of this part shall become effective April 5, 1947.

ROBERT M. LITTLEJOHN,
Administrator.

MARCH 25, 1947.

[F. R. Doc. 47-3304; Filed, Apr. 3, 1947; 10:32 a. m.]

[Reg. 1,[1] Revocation of Order 10]

PART 8301—DESIGNATION OF DISPOSAL AGENCIES AND PROCEDURES FOR REPORTING SURPLUS PROPERTY LOCATED WITHIN THE CONTINENTAL UNITED STATES, ITS TERRITORIES AND POSSESSIONS

APPROVAL OF DELEGATION OF DISPOSAL AUTHORITY BY THE MARITIME COMMISSION TO THE WAR ASSETS ADMINISTRATION FOR MARITIME PERSONAL PROPERTY TO BE SOLD AT SITE SALES

War Assets Administration Regulation 1, Order 10, October 25, 1946, entitled "Approval of Delegation of Disposal Authority by the Maritime Commission to the War Assets Administration for Maritime Personal Property to be Sold at Site Sales" (11 F. R. 12794), is hereby revoked and rescinded.

(Surplus Property Act of 1944, as amended (58 Stat. 765, as amended; 50 U. S. C. App. Sup. 1611); Public Law 181, 79th Congress (59 Stat. 533; 50 U. S. C. App. Sup. 1614a, 1614b); and Executive Order 9689 (11 F. R. 1265))

This revocation shall become effective April 5, 1947.

ROBERT M. LITTLEJOHN,
Administrator.

MARCH 25, 1947.

[F. R. Doc. 47-3305; Filed, Apr. 3, 1947; 10:32 a. m.]

Chapter XXIV—Department of State, Disposal of Surplus Property and Administration of Lend-Lease

[Dept. Reg. 108.43]

PART 8501—DELEGATION OF AUTHORITY TO THE FOREIGN LIQUIDATION COMMISSIONER AND THE DEPUTY FOREIGN LIQUIDATION COMMISSIONER

Sec.
8501.1 Basic delegation.
8501.2 Authority to execute contracts and other documents.
8501.3 Authority to designate deputies and other officers.
8501.4 Assignment of War and Navy officers to field representative of the Commissioner.
8501.5 Maintenance of records.

AUTHORITY: §§ 8501.1 to 8501.5, inclusive, issued under 58 Stat. 765, 59 Stat. 533, Pub. Law 375, 79th Cong., 60 Stat. 168, Pub. Law 584, 79th Cong., 60 Stat. 754; 50 U. S. C. App., Supp. 1611, 1614a, 1614b; E. O. 9630, Sept. 27, 1945, 3 CFR 1945 Supp.

§ 8501.1 *Basic delegation.* Under the general supervision of and in conformity with such directions, orders or instructions as may from time to time be issued by the Secretary of State in the execution of the foreign policies of the United States, and reporting to the Secretary through the Assistant Secretary for Economic Affairs:

(a) The Foreign Liquidation Commissioner (referred to as Commissioner in the regulations in this part) is hereby delegated the entire authority and responsibility now or hereafter vested in the Department of State for the administration and coordination of policies and action in connection with the disposition of all surplus property, including scrap, salvage, waste materials, and property captured from the enemy, for which the Department of State may be responsible;

(b) The Deputy Foreign Liquidation Commissioner (referred to as Deputy Commissioner in the regulations in this part) is hereby delegated authority to serve as Deputy to the Foreign Liquidation Commissioner in all matters relating to the disposal of surplus property, and to exercise all of the authority and perform all of the functions of the Commissioner with respect to such matters in his absence.

§ 8501.2 *Authority to execute contracts and other documents.* The Commissioner and the Deputy Commissioner are authorized to execute such agreements, contracts, and other documents on behalf of the United States or the Department of State as may be necessary or desirable in the performance of the functions delegated to them.

§ 8501.3 *Authority to designate deputies and other officers.*—(a) *Deputies and assistants.* The Commissioner is authorized, with the approval of the Assistant Secretary for Economic Affairs, to designate additional Deputy Commissioners, who may in the order prescribed in the instrument of designation exercise all of the authority and perform all of the functions hereunder of the Commissioner in his absence, and one or more Assistant Commissioners, who may in the order prescribed in the instrument of appointment exercise all of the authority and perform all of the functions of the Commissioner in this part in the absence of the Commissioner and the Deputy Commissioner.

(b) *Other delegations.* The Commissioner is authorized to designate field representatives and to delegate all or any part of his authority and functions in this part hereunder to such representatives, and to any United States Government agency, with the consent of such agency, or, subject to such conditions, directions, and restrictions as

[1] Reg. 1 (12 F. R. 863).

may be prescribed by the Commissioner or his authorized representatives, either in the instrument of delegation or otherwise from time to time, to a person under the complete control of such Government agency. Such delegations may authorize successive redelegations according to the terms of the instrument of delegation. Under this authorization the following types of delegations have been made:

(1) Central Field Commissioners and Field Commissioners have been delegated the power, for or on behalf of the Foreign Liquidation Commissioner, (i) to dispose of all surplus property located in their respective areas for the disposal of which the Department of State may be responsible; (ii) to perform all acts necessary to accomplish the expeditious disposal of such property including the execution of contracts and the employment of personnel and the procurement of materials within the limits of funds available to their respective areas for such purposes; and (iii) to redelegate to deputies and assistants all or any part of their powers with regard to all or any part of the area or property under their jurisdiction in accordance with applicable directives issued by the Foreign Liquidation Commissioner.

(2) The geographic areas under the jurisdiction of the various Central Field Commissioners and Field Commissioners are as follows:

(i) *Central Field Commissioner for Pacific and China.* Those areas lying outside the continental United States, Hawaii, and Alaska (including the Aleutian Islands) west of 141 degrees west longitude and east of 100 degrees east longitude, including, however, all of China, Thailand, and Sumatra.

(ii) *Field Commissioner for Canada; North Atlantic.* Those areas lying outside the continental United States and Alaska east of 141 degrees west, west of 32 degrees west, and north of 33 degrees north, including, however, all of Greenland together with Iceland, Bermuda, and the Bahamas.

(iii) *Central Field Commissioner for Latin America.* Those areas lying outside the continental United States and Puerto Rico east of 141 degrees west, west of 32 degrees west, and south of 33 degrees north, excepting, however, Bermuda and the Bahamas.

(iv) *Central Field Commissioner for Europe.* Those areas lying east of 32 degrees west, west of 60 degrees east, and north of 14 degrees south, excluding, however, (*a*) Greenland and Iceland; (*b*) Areas east of 32 degrees east and south of 37 degrees north; and (*c*) Iran, Iraq, Syria, Turkey, Egypt, Anglo-Egyptian Sudan, Uganda, Tanganyika, Northern Rhodesia, and Angola.

(v) *Field Commissioner for India; Burma.* Those areas lying west of 100 degrees east, and east of 60 degrees east, excluding, however, Thailand, China, Sumatra, and Iran.

(vi) *Central Field Commissioner for Africa, Middle East—Persian Gulf.* Those areas lying west of 60 degrees east, east of 32 degrees east, and south of 37 degrees north, and those areas lying west of 32 degrees east, east of 32 degrees west, and south of 14 degrees south, including, however, Iran, Iraq, Syria, Turkey, Egypt, Anglo-Egyptian Sudan, Uganda, Tanganyika, Northern Rhodesia, and Angola.

(3) The Field Commissioner for Military Programs has been delegated the power, for or on behalf of the Foreign Liquidation Commissioner, to dispose of to other governments surplus military property located within or outside the continental United States, its territories and possessions.

(4) Sales Officers have been delegated limited authority to execute contracts for the sale and transfer of surplus property in accordance with their delegated authority. Sales Officers include those persons who have been delegated authority to negotiate and execute contracts for the sale of specific surplus property, specific types of surplus property, or all surplus property located in specified areas.

(5) The names of all persons holding final authority to act for or on behalf of the Foreign Liquidation Commissioner with respect to the matters described herein are on file in the Office of the Foreign Liquidation Commissioner, Department of State, Washington 25, D. C.

(c) The Commissioner is also authorized to designate to serve, in such representative capacities as may be deemed necessary, such officers and enlisted personnel of military or naval establishments as may be detailed to the Department of State pursuant to Executive Order 9630, dated September 27, 1945.

§ 8501.4 *Assignment of War and Navy officers to field representative of the Commissioner.* The Commissioner or his field representatives are authorized to call upon the War and Navy Departments, and the military commander of any theater of operations, command, department, or base in foreign areas and the naval commander of any area, several areas, or fleet, or the commandant of a naval district, in foreign areas for the assignment within his command to the field representative of the Commissioner, of such military and naval personnel, transportation, and administrative services or facilities as may be required to be furnished by them pursuant to paragraphs 8 and 9 of Executive Order 9630, dated September 27, 1945.

§ 8501.5 *Maintenance of records.* The Commissioner shall maintain records of all his transactions and require that such records be kept by each field representative in the form and manner prescribed by him.

This part shall become effective immediately upon publication in the FEDERAL REGISTER.

[SEAL] DEAN ACHESON,
Acting Secretary of State.

MARCH 28, 1947.

[F. R. Doc. 47-3234; Filed, Apr. 3, 1947; 8:48 a. m.]

TITLE 38—PENSIONS, BONUSES, AND VETERANS' RELIEF

Chapter I—Veterans Administration

PART 10—INSURANCE

REINSTATEMENT

§ 10.3080 *Application and medical evidence.* The applicant for reinstatement of United States Government Life Insurance must furnish during his lifetime, and before becoming totally and permanently disabled, and within the three calendar months including the calender month for which the unpaid premium was due, a written application signed by him which shall state that he is in as good health as at date of lapse, or after the expiration of the three calendar months, a written application signed by him that he is in good health, in accordance with the requirements of the particular case; and in addition the applicant shall furnish such evidence relative to his physical condition as may be required by the Administrator of Veterans Affairs, and on such forms as may be prescribed: *Provided,* That if the insurance becomes a claim after tender of the amount of the premiums required but before full compliance with the requirements of this paragraph, and the applicant was in the required state of health at the date that he made the tender of the amount of premiums, and that there is a satisfactory reason for his noncompliance, the director, underwriting service may, if the applicant be dead, waive any or all of the requirements of this section, or, if the applicant be living, allow compliance with this section, as of the date required amount of premiums was received by the Veterans Administration. (Secs. 5, 300, 301, 43 Stat. 608, 624, as amended; secs. 1, 2, 46 Stat. 1016; 38 U. S. C. 11, 11a, 426, 511, 512)

[SEAL] OMAR N. BRADLEY,
General, U. S. Army,
Administrator of Veterans' Affairs.

APRIL 4, 1947.

[F. R. Doc. 47-2366; Filed, Apr. 3, 1947; 8:49 a. m.]

PROPOSED RULE MAKING

DEPARTMENT OF AGRICULTURE

Production and Marketing Administration

[7 CFR, Part 946]

[Docket No. AO-123-A6]

HANDLING OF MILK IN LOUISVILLE, KY., MARKETING AREA

NOTICE OF HEARING ON PROPOSED AMENDMENTS TO TENTATIVELY APPROVED MARKETING AGREEMENT

Pursuant to the Agricultural Marketing Agreement Act of 1937, as amended (7 U. S. C., 601 et seq.), and in accordance with the applicable rules of practice and procedure, as amended (7 CFR, Cum. Supp. 900.1 et seq.; 10 F. R. 11791, 11 F. R. 7737, 12 F. R. 1159), notice is hereby given of a public hearing to be held at the Henry Clay Hotel, Louisville, Kentucky, beginning at 10:00 a. m., c. s. t., April 28, 1947, for the purpose of receiving with respect to the proposed amendments to the tentatively approved marketing agreement, as amended, and the order, as amended, regulating the handling of milk in the Louisville, Kentucky, milk marketing area (11 F. R. 11121). These proposed amendments have not received the approval of the Secretary of Agriculture.

The following amendments have been proposed:

By the Dairy Branch, Production and Marketing Administration:

1. Amend § 946.1 by adding a paragraph (j) to read as follows:

(j) "Department of Agriculture" means the United States Department of Agriculture or such other Federal agency authorized to perform the price reporting functions specified in §§ 946.4 and 946.8 (f).

By the Rolling Green Dairy, Scottsburg, Indiana:

2. Amend § 946.1 (c) by deleting the towns of Speed, Sellersburg, and Memphis in Clark County, Indiana, from the Louisville, Kentucky, marketing area.

By the Dairy Branch, Production and Marketing Administration:

3. Amend § 946.2 (b) by adding two subparagraphs to read as follows:

(3) Make rules and regulations to effectuate the terms and provisions hereof; and

(4) Recommend to the Secretary amendments hereto.

4. Amend § 946.2 (c) by adding a subparagraph to read as follows:

(8) Prepare and disseminate for the benefit of producers, consumers, and handlers, such statistics and information concerning the operation hereof as does not reveal confidential information.

By the Falls Cities Cooperative Milk Producers Association:

5. Delete § 946.3 (d) and substitute the following:

(d) *Computation of class volumes.* For each delivery period the market administrator shall correct for mathematical and for other obvious errors the report submitted by each handler and compute from the corrected report the amount of Class I milk, Class II milk, and Class III milk as follows:

(1) Determine (i) the total pounds of milk received from producers (including the handler's own production), and (ii) the total pounds of milk, skim milk, and other milk products received from other handlers, received as emergency milk, and received from other sources; add together the resulting amounts.

(2) Determine the total pounds of butterfat received by multiplying by its respective average butterfat test the milk, skim milk, and other milk products determined under subparagraph (1) of this paragraph; add together the resulting amounts.

(3) Determine the total pounds of Class I milk as follows:

(i) Convert to quarts the quantity of milk and skim milk disposed of in the form of milk, buttermilk, and milk drinks, whether plain or flavored, and multiply by 2.15;

(ii) Multiply the result by the average butterfat test thereof; and

(iii) If the quantity of butterfat so computed when added to the pounds of butterfat in Class II milk and Class III milk computed pursuant to subparagraphs (4) (ii) and (5) (ii) of this paragraph is less than the total pounds of butterfat received, computed in accordance with subparagraph (2) of this paragraph, the butterfat shrinkage on milk from producers which exceeds 2 percent of such butterfat shall be divided by 3.8 percent and added to the quantity determined pursuant to subdivision (i) of this subparagraph.

(4) Determine the total pounds of Class II milk as follows:

(i) Multiply the actual weight of each of the products of Class II milk by its average butterfat test;

(ii) Add together the resulting amounts; and

(iii) Divide the result obtained in subdivision (ii) of this subparagraph by 3.8 percent.

(5) Determine the pounds of Class III milk as follows:

(i) Compute the total pounds of butterfat used to produce a product other than those specified in Class I milk and Class II milk;

(ii) Add together the resulting amounts;

(iii) Subtract the total pounds of butterfat in Class I milk and Class II milk, computed pursuant to subparagraphs (3) (ii) and (4) (ii) of this paragraph, and the total pounds of butterfat computed pursuant to subdivision (ii) of this subparagraph, from the total pounds of butterfat computed pursuant to subparagraph (2) of this paragraph, which resulting quantity shall be allowed as plant shrinkage for the purpose of this paragraph (but in no event shall such plant shrinkage allowance exceed 2 percent of butterfat in milk received from producers, plus actual plant shrinkage of butterfat received from sources other than producers and handlers, including emergency milk) and shall be added to the result obtained in subdivision (ii) of this subparagraph; and

(iv) Divide the result obtained in subdivision (iii) of this subparagraph by 3.8 percent.

By the Louisville Milk Distributors Association:

6. Delete the provisions of § 946.3 (b), and substitute therefor the following:

(b) *Classes of utilization.* The classes of utilization of milk shall be as follows:

(1) Class I milk shall be all milk disposed of as milk and/or milk drinks having a butterfat content in excess of 1 percent, and all milk not specifically accounted for as Class II milk, Class III milk, and Class IV milk.

(2) Class II milk shall be all milk disposed of as cream (for consumption as cream) including any cream product disposed of in fluid form which contains less than the minimum butterfat content required for fluid cream, and all skimmed milk disposed of as buttermilk or milk drinks, whether plain or flavored and not disposed of in Class I.

(3) Class III milk shall be all milk, skim milk, and cream accounted for (i) as used to produce a product other than those specified in Class I milk, Class II milk, and Class IV milk, (ii) as actual plant shrinkage of butterfat in milk received from producers, but not to exceed 3 percent of such receipts of butterfat, and (iii) as actual plant shrinkage of butterfat in milk, skim milk, and cream received from sources other than producers and handlers, including emergency milk: *Provided,* That if milk is diverted by a handler to a plant of another handler without first having been received for purposes of weighing and testing in the diverting handler's plant, the quantity of butterfat in such milk shall be included in the butterfat receipts of the second handler in computing his plant shrinkage and shall be excluded from the butterfat receipts of the diverting handler in the latter's plant shrinkage computation; *And provided further,* That (*a*) if milk from producers is utilized as milk, skim milk or cream in conjunction with milk, skim milk, or cream from sources other than producers or other handlers, the shrinkage allocated to the milk from producers shall not exceed its pro rata share computed on the basis of producer milk available for Class III and ungraded receipts, and (*b*) if milk from producers is transferred as milk, skim milk, or cream under supporting transfer records satisfactory to the market administrator, to a plant of a handler from which no milk of producers is disposed of as fluid milk in the marketing area, the shrinkage on the aforesaid transferred portion shall be computed on a pro rata basis with all milk,

skim milk, and cream utilized in the latter plant and added to the shrinkage on producers' milk handled in the handler's fluid milk plant.

(4) Class IV milk shall be that portion of the milk used to produce butter by a handler reporting utilization in Class III in excess of 10 percent of such handler's total receipts during the reporting period. No handler shall be permitted in any delivery period to report an amount of milk utilized in Class IV in excess of an amount equal to 10 percent of said handler's reported Class I sales for said delivery period.

By the Dairy Branch, Production and Marketing Administration:

7. Amend § 946.3 (c) by adding a subparagraph to read as follows:

(4) Milk, skim milk, and cream transferred or diverted by a handler from a plant, described under § 946.1 (e) (1) or (2), of such handler, to any other plant of such handler shall be Class III milk: *Provided,* That if milk, skim milk, or cream so transferred or diverted to such plant from which milk, skim milk, or cream is disposed of for human consumption as any product specified in paragraph (b) (1) or (b) (2) of this section, such milk, skim milk, or cream so transferred shall be classified on the basis of its pro rata share of the disposition of all receipts of milk, skim milk, and cream from the latter plant.

By the Louisville Milk Distributors Association:

8. Delete the provisions of § 946.3 (d) and substitute therefor the following:

(d) *Computation of class volumes.* For each delivery period the market administrator shall correct for mathematical and for other obvious errors the report submitted by each handler and compute from the corrected report the amount of Class I milk, Class II milk, and Class IV milk, as follows:

(1) Determine (i) the total pounds of milk received from producers (including the handler's own production), and (ii) the total pounds of milk, skim milk, and other milk products received from other handlers, received as emergency milk, and received from other sources, and add together the resulting amounts.

(2) Determine the total pounds of butterfat received by multiplying by its respective average butterfat test the milk, skim milk, and other milk products determined under subparagraph (1) of this paragraph; add together the resulting amounts.

(3) Determine the total pounds of Class I milk as follows:

(i) Convert to quarts the quantity of milk and skim milk disposed of in the form of milk, buttermilk and milk drinks, whether plain or flavored, and multiply by 2.15;

(ii) Multiply the result by the average butterfat test thereof; then

(iii) Divide the result obtained by the average butterfat test of receipts from producers to obtain total milk pounds.

(iv) If the quantity of butterfat so computed when added to the pounds of butterfat in Class II milk, Class III milk, and Class IV milk computed pursuant to subparagraphs (4) (ii), (5) (ii), and (6) of this paragraph is less than the total pounds of butterfat received, computed in accordance with subparagraph (2) of this paragraph, the butterfat shrinkage on milk from producers which exceeds 3 percent of such butterfat shall be divided by the average test of receipts from producers and added to the quantity determined pursuant to subdivision (i) of this subparagraph.

(4) Determine the total pounds of Class II milk as follows:

(i) Multiply the actual weight of each of the products of Class II milk by its average butterfat test;

(ii) Add together the resulting amounts; and

(iii) Divide the result obtained in subdivision (ii) of this subparagraph by the average test of receipts from producers.

(5) Determine the pounds of Class III milk as follows:

(i) Compute the total pounds of butterfat used to produce a product other than those specified in Class I milk, Class II milk, and Class IV milk;

(ii) Add together the resulting amounts;

(iii) Subtract the total pounds of butterfat in Class I milk, Class II milk, and Class IV milk, computed pursuant to subparagraphs (3) (ii), (4) (ii), and (6) of this paragraph, and the total pounds of butterfat computed pursuant to subdivision (ii) of this subparagraph, from the total pounds of butterfat computed pursuant to subparagraph (2) of this paragraph, which resulting quantity shall be allowed as plant shrinkage for the purpose of this paragraph (but in no event shall such plant shrinkage allowance exceed 3 percent of butterfat in milk received from producers, plus actual plant shrinkage of butterfat received handlers, including emergency milk) and shall be added to the result obtained in subdivision (ii) of this subparagraph; from sources other than producers and and

(iv) Divide the result obtained in subdivision (iii) of this subparagraph by the average butterfat test of receipts from producers.

(6) Determine the total pounds of Class IV milk as follows:

(i) Divide by the average test of receipts from producers the total pounds of butterfat manufactured into butter or sold to a butter manufacturer to determine hundredweight pounds of milk used for this purpose by each handler, (ii) add together the resulting amounts; (iii) determine the total pounds of Class III milk in excess of 10 percent of the total pounds of milk received from producers (including the handler's own production), received from other handlers, received as emergency milk and received from other sources; (iv) determine the total pounds of milk equal to 10 percent of each handler's Class I sales; (v) when the total pounds of milk as determined in subdivision (ii) of this subparagraph exceed the total pounds of milk as determined in subdivision (iii) of this subparagraph such total pounds of milk shall be considered to be each handler's Class IV usage provided such total pounds of milk do not exceed the total pounds of milk as determined in subdivision (iv) of this subparagraph.

9. Delete the provisions of § 946.3 (e).

10. Delete the provisions of § 946.3 (f) and substitute therefor the following:

(f) *Allocation of milk classified.* The amount remaining in each class after making the following computations shall be the amount in such class allocated to milk received from producers:

(1) Subtract from the total pounds of milk computed for each class, in series beginning with the lower priced Class III milk, the total pounds, except emergency milk, received from sources other than producers and handlers;

(2) Subtract from the remaining pounds of milk computed for each class the total pounds of emergency milk assigned to such class;

(3) Subtract from the remaining pounds of milk computed for each class the total pounds received from other handlers and assigned to such class: *Provided,* That if the total pounds to be subtracted from Class II milk or Class III milk is greater than the remaining pounds of milk in such class, the balance shall be subtracted from the remaining pounds of milk in the next higher priced class.

By the Falls Cities Cooperative Milk Producers Association:

11. Delete § 946.4 (a) and substitute the following:

§ 946.4 *Minimum prices*—(a) *Class prices.* Subject to the provisions of paragraph (b), (c), (d), and (e) of this section, each handler shall pay producers, at the time and in the manner set forth in § 946.8, not less than the prices per hundredweight computed as follows by the market administrator for the respective quantities of Class I milk, Class II milk, and Class III milk, computed pursuant to § 946.3 (e) and (f):

(1) *Class I milk.* The price for Class I milk shall be the price determined pursuant to subparagraph (5) of this paragraph, plus $1.05.

(2) *Class II milk.* The price for Class II milk shall be the price determined pursuant to subparagraph (5) of this paragraph, plus $0.50.

(3) *Class III milk.* Except as set forth in subparagraph (4) of this paragraph, the price for Class III milk shall be the price resulting from the following computation: determine, on the basis of milk of 4 percent butterfat content, the arithmetic average of the basic, or field prices per hundredweight reported by, and ascertained by the market administrator to have been paid by, the following concerns at the manufacturing plants or places listed below for ungraded milk received during the delivery period:

Concern and Location

Kraft Cheese Co., Lawrenceburg, Ky.
Armour Creameries, Elizabethtown, Ky.
Armour Creameries, Springfield, Ky.
Kraft Cheese Co., Salem, Ind.
Ewing-Von Allmen Co., Corydon, Ind.
Ewing-Von Allmen Co., Madison, Ind.
Producers' Dairy Marketing Association, Orleans, Ind.

and subtract an amount computed by multiplying the average wholesale price

per pound of 92-score butter in the Chicago market, as reported by the agency described in paragraph (a) (3) (i) of this section for the delivery period during which the milk was received, by 20 percent: *Provided,* That if the price so determined is less than the price computed in accordance with the following formula, such formula price shall be used:

(i) Multiply by 3.8 the average wholesale price per pound of 92-score butter in the Chicago market as reported by the United States Department of Agriculture (or by such other Federal agency as may hereafter be authorized to perform this price reporting function) for the delivery period during which such milk was received;

(ii) Add 20 percent thereof; and

(iii) Add 3½ cents per hundredweight for each full one-half cent that the price of nonfat dry milk solids by spray process for human consumption is above 5½ cents per pound. For the purpose of this formula the price per pound of nonfat dry milk solids to be used shall be the average of the carlot prices by spray process for human consumption, published by the agency described in subdivision (i) of this subparagraph, for the Chicago market during the delivery period, including in such average the quotations published for any fractional part of the previous delivery period which were not published and available for the price determination of such milk solids for the previous delivery period. In the event the carlot prices for nonfat dry milk solids by spray process for human consumption, f. o. b. manufacturing plants, are not so published, the average of the carlot prices for such milk solids, delivered at Chicago, as published by any such agency, shall be used, and the following shall be used in lieu of the computation provided under subdivision (iii) of this subparagraph add 3½ cents per hundredweight for each full one-half cent that the price of such nonfat dry milk solids for human consumption delivered at Chicago, is above 6½ cents per pound.

(4) In the case of butter made from producers' milk received during the delivery periods of April, May, and June, which as milk equivalent is not in excess of 10 percent of the handler's Class I milk computed pursuant to § 946.3 (f), the price shall be that resulting from the following computation: Multiply by 3.8 the average wholesale price of 92-score butter in the Chicago market, as reported by the agency described in subparagraph (3) (i) of this paragraph for the delivery period, and add 20 percent thereof.

(5) *Basic price.* The basic price per hundredweight of milk to be used in computing the minimum prices for Class I milk and Class II milk, set forth in subparagraphs (1) and (2) of this paragraph, shall be the price computed pursuant to subparagraph (3) of this paragraph plus 15 cents or that resulting from the following formula, whichever is the higher: to the average of the basic (or field) prices reported to have been paid, or to be paid, for milk for 3.5 percent butterfat content received during the delivery period at the following places for which prices are reported to the market administrator by the companies listed below or by the agency described in subparagraph (3) (i) of this paragraph:

Companies and Locations

Borden Co., Black Creek, Wis.
Borden Co., Greenville, Wis.
Borden Co., Mt. Pleasant, Mich.
Borden Co., New London, Wis.
Borden Co., Orfordville, Wis.
Carnation Co., Berlin, Wis.
Carnation Co., Jefferson, Wis.
Carnation Co., Chilton, Wis.
Carnation Co., Oconomowoc, Wis.
Carnation Co., Richland Center, Wis.
Carnation Co., Sparta, Mich.
Pet Milk Co., Belleville, Wis.
Pet Milk Co., Coopersville, Mich.
Pet Milk Co., Hudson, Mich.
Pet Milk Co., New Glarus, Wis.
Pet Milk Co., Wayland, Mich.
White House Milk Co., Manitowoc, Wis.
White House Milk Co., West Bend, Wis.

add an amount computed by multiplying the butterfat differential, determined pursuant to § 946.8 (f), by 3.

(6) The prices used in determining the average manufacturing plant price pursuant to subparagraph (3) or (5) of this paragraph shall be those quoted for milk received at the respective plants, without deductions for hauling or other charges to be paid by the farm shipper.

12. Delete § 946.4 (b) and substitute the following:

(b) *Price of Class I milk for relief distribution.* For Class I milk delivered by a handler to the residence of a relief client certified by a recognized relief agency, charged to such an agency, or disposed of by a handler under a program approved by the Secretary for the sale or disposition of milk to low-income consumers, including persons on relief, such handler shall pay not less than the price for Class I milk minus 55 cents.

13. Delete § 946.4 (c) and substitute the following:

(c) *Butterfat differential to handlers.* If any handler has received from producers milk containing more or less than 3.8 percent of butterfat, such handler shall add or deduct, per hundredweight of milk, for each one-tenth of 1 percent of butterfat above or below 3.8 percent, an amount computed by the market administrator as follows: To the average wholesale price per pound of 92-score butter in the Chicago market, as reported by the agency described in paragraph (a) (3) (i) of this section for the delivery period during which the milk was received, add 20 percent, and divide the result by 10.

14. Delete § 946.4 (d) and substitute therefor the following:

(d) *Class volume reconciliation adjustment.* For the amount of milk involved in any reconciliation of class volumes of milk, pursuant to § 946.3 (e), the handler shall be debited or credited, as the case may be, at the higher Class III price: *Provided,* That if such handler received from producers milk with an average test of butterfat of 3.8 percent or less and disposed of no milk, skim milk, or cream as a Class III milk product, such debit or credit, as the case may be, shall be made at the Class II price.

By the Louisville Milk Distributors Association:

15. Delete the provisions of § 946.4 and substitute therefor the following:

§ 946.4 *Minimum prices*—(a) *Class prices.* Subject to the provisions of paragraphs (b), (c), (d), and (e) of this section, each handler shall pay producers, at the time and in the manner set forth in § 946.8, not less than the prices per hundredweight computed as follows by the market administrator for the respective quantities of Class I milk, Class II milk, Class III milk, and Class IV milk computed pursuant to § 946.3 (f):

(1) *Class I milk.* The price for Class I milk shall be the price determined pursuant to subparagraph (5) of this paragraph, plus $0.90.

(2) *Class II milk.* The price for Class II milk shall be the price determined pursuant to subparagraph (5) of this paragraph, plus $0.40.

(3) *Class III milk.* The price for Class III milk shall be the price resulting from the following computation: Determine, on the basis of milk of 4 percent butterfat content, the arithmetic average of the basic, or field, prices per hundredweight reported by, and ascertained by the market administrator to have been paid by, the following concerns at the manufacturing plants or places listed below for ungraded milk received during the delivery period:

Concern and Location

Kraft Foods Co., Lawrenceburg, Ky.
Armour Creameries, Elizabethtown, Ky.
Armour Creameries, Springfield, Ky.
Kraft Foods Co., Salem, Ind.
Ewing Von Allmen Dairy Co., Corydon, Ind.
Ewing Von Allmen Dairy Co., Madison, Ind.
Producers' Dairy Marketing Association, Orleans, Ind.

Provided, That if the price so determined is less than the price computed in accordance with the following formula, such formula price shall be used:

(i) Multiply by 4 the average wholesale price per pound of 92-score butter in the Chicago market as reported by the United States Department of Agriculture (or by such other Federal agency as may hereafter be authorized to perform this price reporting function) for the delivery period during which such milk was received;

(ii) Add 20 percent thereof; and

(iii) Add 3½ cents per hundredweight for each full one-half cent that the price of nonfat dry milk solids by roller process for human consumption is above 5½ cents per pound. For the purpose of this formula the price per pound of nonfat dry milk solids to be used shall be the average of the carlot prices by roller process for human consumption, published by the agency described in subdivision (i) of this subparagraph, for the Chicago market during the delivery period, including in such average the quotations published for any fractional part of the previous delivery period which were not published and available for the price determination of such milk solids

for the previous delivery period. In the event the carlot prices for nonfat dry milk solids by roller process for human consumption, f. o. b. manufacturing plants, are not so published, the average of the carlot prices for such milk solids, delivered at Chicago as published by any such agency, shall be used, and the following shall be used in lieu of the computation provided under subdivision (iii) of this subparagraph: Add 3½ cents per hundredweight for each full one-half cent that the price of such nonfat dry milk solids for human consumption delivered at Chicago, is above 7½ cents per pound.

(4) *Class IV milk.* The price for Class IV milk shall be the price determined per hundredweight of milk testing 4 percent butterfat by multiplying the price of 92-score butter (Chicago market as reported by the United States Department of Agriculture for the delivery period during which said milk was delivered) by 4 and adding thereto 20 percent.

16. Delete the provisions of § 946.4 (a) (5) and substitute therefor the following:

(5) *Basic price.* The basic price of milk to be used in computing the minimum prices for Class I milk and Class II milk shall be an average of the price for the current delivery period and the previous delivery period.

17. Delete the provisions of § 946.4 (a) (6) and substitute therefor the following:

(6) The prices used in determining the average manufacturing plant price pursuant to subparagraph (3) of this paragraph shall be those quoted for milk received at the respective plants, without deductions for hauling or other charges to be paid by the farm shipper.

18. Amend § 946.4 by deleting paragraphs (d) and (e), and substituting therefor the following:

(d) *Sales outside marketing area.* The price to be paid by a handler for Class I milk disposed of outside the marketing area, in lieu of the price otherwise applicable pursuant to this section, shall be the price, as ascertained by the market administrator, which is being paid for milk of an equivalent use in the market where such milk is disposed of: *Provided,* That such Class I price as ascertained by the market administrator shall be subject to a transportation adjustment of 1½ cents per hundredweight of such milk for every 15 miles or fraction thereof from the shipping point where such milk is received from producers to the market where such milk is utilized as Class I milk: *Provided further,* That such Class I price, as ascertained by the market administrator, less the adjustment for transportation shall not be lower than the Class I price as set forth in § 946.4 (a) (1) minus 40 cents.

By the Dairy Branch, Production and Marketing Administration:

19. Amend § 946.6 by adding a paragraph (d) to read as follows:

(d) Milk received at the plant of a handler, the handling of which the Secretary determines to be subject to the pricing and payment provisions of any other Federal milk marketing agreement or order issued pursuant to the act for any fluid milk marketing area shall not be subject to the pricing and payment provisions hereof.

By the Louisville Milk Distributors Association:

20. Delete the provisions of § 946.7 (a) and substitute therefor the following:

(a) *Computation of value for each handler.* For each delivery period the market administrator shall compute, subject to the provisions of § 946.6 (b) and (c), the value of milk of producers received by each handler, by multiplying the quantity in each class by the price applicable to such class and by adding together the resulting class values: *Provided,* That with respect to butter made from producers' milk, but not to exceed as milk equivalent 10 percent of such handler's Class I milk computed pursuant to § 946.3 (f), the applicable price shall be that computed pursuant to § 946.4 (4). If such handler utilizes milk, skim milk, or cream from sources other than producers or other handlers in milk products, the amount of butter allocated to milk from producers shall be a pro rata share based upon the respective volumes from each source utilized in milk products.

By the Falls Cities Cooperative Milk Producers Association:

21. Delete § 946.7 (b) (1) and (2) and substitute the following:

(b) *Computation and announcement of uniform prices.* The market administrator shall compute and announce the uniform price per hundredweight of producer milk containing 3.8 percent of butterfat for each delivery period, as follows:

(1) Combine into one total the respective values computed pursuant to paragraph (a) of this section, for all handlers who made the report prescribed by § 946.5 (a) for such delivery period, except those in default of payments required pursuant to § 946.8 (c) for the preceding delivery period;

(2) Subtract, if the average butterfat content of all milk received from producers is in excess of 3.8 percent, or add, if such average butterfat content is less than 3.8 percent, the total value of the butterfat differential applicable pursuant to § 946.8 (f).

By the Louisville Milk Distributors Association:

22. Amend § 946.7 (b) by designating the present subparagraph (3) as (i) and adding thereto the following subparagraph:

(ii) Add for each of the delivery periods of September, October, and November an amount equal to one-third of the aggregate amount withheld pursuant to § 946.7 (b) (3) (i).

By the Louisville Milk Distributors Association:

23. Amend § 946.8 (b) by deleting therefrom the proviso clause as follows: *"Provided,* That payments due any handler shall be off-set by payments due from such handler."

24. Delete § 946.8 (d) (2).

By the Fall Cities Cooperative Milk Producers Associations:

25. Delete § 946.8 (f) and substitute therefor the following:

(f) *Butterfat differential.* In making payment to each producer, pursuant to paragraph (a) of this section, each handler shall add to the uniform price not less than, or subtract from the uniform price not more than, as the case may be, for each one-tenth of 1 percent of butterfat content above or below 3.8 percent in milk received from such producer, the amount as shown in the schedule below for the butter price range in which falls the average wholesale price per pound of 92-score butter in the Chicago market, as reported by the agency described in § 946.4 (a) (3) (i), for the delivery period during which such milk was received:

Butter price range (cents):	*Butterfat differential (cents)*
17.499 or less	2
17.50–22.499	2½
22.50–27.499	3
27.50–32.499	3½
32.50–37.499	4
37.50–42.499	4½
42.50–47.499	5
47.50–52.499	5½
52.50–57.499	6
57.50–62.499	6½
62.50–67.499	7
67.50–72.499	7½
72.50–77.499	8
77.50–82.499	8½
82.50–87.499	9
87.50–92.499	9½
92.50 and over	10

By the Louisville Milk Distributors Association:

26. Amend § 946.10, Expense of administration, by designating the present paragraph as (a) and adding a new paragraph thereto as follows:

(b) The funds so collected shall be impressed with a trust under the custody of the market administrator and shall be expended in accordance with applicable provisions of the order and, at least quarterly, a detailed account of income and disbursements shall be made available to the regulated handlers.

By the Dairy Branch, Production and Marketing Administration:

27. Delete § 946.10 and substitute therefor the following:

§ 946.10 *Expense of administration.* As his pro rata share of the expense of administration hereof, each handler, on or before the 15th day after the end of each delivery period, shall pay to the market administrator 2 cents per hundredweight or such lesser amount as the Secretary may prescribe with respect to all milk purchased or received by such handler, during such delivery period, from producers, including that received from such handler's own farm production, and all milk, skim milk, and cream received from sources other than producers and other handlers during the delivery period. Each cooperative association which is a handler shall pay such

pro rata share of expense on only that milk of producers caused to be delivered by such cooperative association to a plant from which no milk is disposed of in the marketing area.

General proposals by the Louisville Milk Distributors Association:

28. Amend the present method of accounting for milk by substituting therefor in each of the sections, subsections, and classifications the appropriate language to establish for the Louisville milk marketing area the "skim-butterfat" basis of reporting and accounting for utilization in each class, under such terms and conditions as will effectuate a price to handlers in accordance with specific price proposals incorporated in the foregoing proposals of such association.

By the Dairy Branch, Production and Marketing Administration:

29. Make such other changes as may be required to make the entire marketing agreement or order conform with any amendments thereto which may result from this hearing.

Copies of this notice of hearing and of the tentatively approved marketing agreement and order, now in effect, may be procured from the market administrator, 1235 Starks Building, Louisville 2, Kentucky, or from the Hearing Clerk, Office of the Solicitor, United States Department of Agriculture, Room 0306, South Building, Washington 25, D. C., or may be there inspected.

Dated: March 31, 1947.

[SEAL] E. A. MEYER,
Assistant Administrator.

[F. R. Doc. 47-3241; Filed, Apr. 3, 1947; 8:45 a. m.]

[7 CFR, Part 967]

[Docket No. AO-170-A2]

HANDLING OF MILK IN LA PORTE-ST. JOSEPH COUNTIES, INDIANA, MARKETING AREA

NOTICE OF HEARING ON PROPOSED AMENDMENTS TO TENTATIVELY APPROVED MARKETING AGREEMENT

Pursuant to the Agricultural Marketing Agreement Act of 1937, as amended (7 U. S. C., 601 et seq.), and in accordance with the applicable rules of practice and procedure, as amended (7 CFR, Cum. Supp., 900.1 et seq.; 10 F. R. 11791, 11 F. R. 7737, 12 F. R. 1159), notice is hereby given of a public hearing to be held at the Oliver Hotel, South Bend, Indiana, beginning at 10:00 a. m., c. s. t., April 28, 1947, for the purpose of receiving evidence with respect to proposed amendments to the tentatively approved marketing agreement and the order regulating the handling of milk in the St. Joseph County, Indiana, milk marketing area (8 F. R. 8790). These proposed amendments have not received the approval of the Secretary of Agriculture.

The following amendments have been proposed:

By the Dairy Branch, Production and Marketing Administration:

1. Delete the provisions of § 967.1 and substitute therefor the following:

§ 967.1 *Definitions.* The following terms mean:

(a) "Act" means Public Act No. 10, 73d Congress, as amended and as reenacted and amended by the Agricultural Marketing Agreement Act of 1937, as amended (7 U. S. C., 601 et seq.).

(b) "Secretary" means the Secretary of Agriculture or such other officer or employee of the United States authorized to exercise the powers or to perform the duties of the said Secretary of Agriculture.

(c) "Department of Agriculture" means the United States Department of Agriculture.

(d) "Person" means any individual, partnership, corporation, association, or any other business unit.

(e) "Delivery period" means the calendar month or the total portion thereof during which this order is in effect.

(f) "Cooperative Association" means any cooperative association of producers which the Secretary determines, after application by the association:

(1) To be qualified under the provisions of the act of Congress of February 18, 1922, as amended, known as the "Capper-Volstead Act"; and

(2) To have full authority in the sale of milk of its members and to be engaged in making collective sales or marketing milk or its products for its members.

(g) "St. Joseph-La Porte County, Indiana, marketing area," hereinafter called the "marketing area," means all territory within the geographical limits of St. Joseph County, Indiana, except the townships of Olive, Liberty, and Lincoln; and all territory within the geographical limits of La Porte County, Indiana.

(h) "Approved plant" means a milk plant which is approved by the health authorities of the municipalities of South Bend, Mishawaka, La Porte, or Michigan City, Indiana, and from which a route is operated wholly or partially within the marketing area.

(i) "Producer" means any person, having certification issued by the applicable health authority in the marketing area to produce milk for disposition within the marketing area in the form of fluid milk, who produces milk which is received at an approved plant.

(j) "Producer milk" means milk produced by one or more producers under the conditions set forth in subdivision (i) of this subparagraph.

(k) "Emergency milk" means milk, skim milk, or cream received from sources other than producers or handlers under an emergency permit to receive such milk, skim milk, or cream issued by the appropriate health authority.

(l) "Route" means a delivery (including at a plant store) of milk or milk drinks whether plain or flavored, in fluid form to a wholesale or retail stop(s) other than to a milk processing or distributing plant(s).

(m) "Handler" means (1) a person who operates an approved plant, or (2) a cooperative association with respect to: (i) Milk caused by it to be delivered from producers' farms to a plant or plants described in subparagraph (1) of this paragraph, for which milk such association is authorized to receive payment; or (ii) milk customarily received as producer milk at an approved plant which is diverted by such association on its account to the plant of a nonhandler.

(n) "Nonhandler" means any person other than a handler who operates a milk processing or distributing plant which is not an approved plant.

(o) "Producer-handler" means any person who produces milk, but receives no milk from other producers and operates an approved plant.

By the Pure Milk Association:

2. Amend § 967.1 (f) to read:

(f) "Producer" means any person who under a dairy farm inspection report issued by the health authorities of either South Bend or Mishawaka, Indiana, produces milk which is received at an approved plant: *Provided,* That upon the first day of the second month after any such report is revoked, and continuing for not more than three (3) months during such revocation any milk which is received from such producer shall be termed degraded milk. After such three (3) months, milk received from such producer shall be considered as milk from other sources.

3. Amend § 967.1 to include:

(k) "Milk from other sources" means milk, skim milk, or cream received from sources other than producers or handlers without a permit issued by either of the health authorities referred to in paragraph (e) of this section.

By Reliable Dairy Company, Inc., Producers Dairy, Inc., City Dairy Company, Inc., Suabedissen-Wittner Dairy, Inc., National Milk Company, Inc., Mishawaka Farmers Dairy, Inc., Best Ever Dairy, Inc., Fertile Acres Dairy, Indiana Dairy Company, Debeck's Sanitary Dairy, West End Dairy, Riverside Dairy Company, South Bend Pure Milk Company, Coussens Dairy, and Oak Ridge Dairy and Creamery, hereinafter referred to as the Reliable Dairy Company, Inc. et al.

4. Delete § 967.1 (c) and substitute therefor the following:

(c) "St. Joseph County, Indiana, marketing area," hereinafter called the "marketing area" means all municipal corporations and unincorporated territory with the geographical limits of St. Joseph County, Indiana, excepting the townships of Olive, Liberty, and Lincoln, and all of the territory in Bertrand and Niles Townships, Berrien County, Michigan; and Milton Township and Ontwa Township, Cass County, Michigan, excepting all territory within the corporation limits of Niles, Michigan.

5. Delete § 967.1 (e) and substitute therefor the following:

(e) "Plant" means any plant which disposes of milk in the marketing area.

6. Delete § 967.1 (f) and substitute therefore the following:

(f) "Producer" means any person who produces milk which is received at a plant.

7. Delete § 967.1 (j) and substitute therefor the following:

(j) "Supplementary milk" means milk, skim milk, or cream received from sources other than producers or handlers.

8. Amend § 967.1 by adding a new paragraph (k) as follows:

(k) "Milk" means the lacteal secretion obtained by the milking of one or more cows, whether in the original or in any processed form, including cream, buttermilk, and skim milk intended for human consumption.

By the Dairy Branch, Production and Marketing Administration:

9. Delete the provisions of § 967.2 and substitute therefor the following:

§ 967.2 *Market administrator*—(a) *Designation.* The agency for the administration hereof shall be a market administrator, selected by the Secretary, who shall be entitled to such compensation as may be determined by, and shall be subject to removal at the discretion of, the Secretary.

(b) *Powers.* The market administrator shall have the following powers with respect to this order:

(1) To administer its terms and provisions;

(2) To receive, investigate, and report to the Secretary complaints of violations;

(3) To make rules and regulations to effectuate its terms and provisions; and

(4) To recommend amendments to the Secretary.

(c) *Duties.* The market administrator shall perform all duties necessary to administer the terms and provisions of this order, including, but not limited to, the following:

(1) Within 30 days following the date on which he enters upon his duties, or such lesser period as may be prescribed by the Secretary, execute and deliver to the Secretary a bond, effective as of the date on which he enters upon such duties and conditioned upon the faithful performance of such duties, in an amount and with surety thereon satisfactory to the Secretary;

(2) Employ and fix the compensation of such persons as may be necessary to enable him to administer its terms and provisions;

(3) Obtain, in an amount and with surety thereon satisfactory to the Secretary, a bond covering each employee who handles funds entrusted to the market administrator;

(4) Pay, out of the funds provided by § 967.9:

(i) The cost of his bond and of the bonds of his employees,

(ii) His own compensation, and

(iii) All other expenses, except those incurred under § 967.10, necessarily incurred by him in the maintenance and functioning of his office and in the performance of his duties;

(5) Keep such books and records as will clearly reflect the transactions provided for herein, and, upon request by the Secretary surrender the same to such other person as the Secretary may designate;

(6) Publicly announce, unless otherwise directed by the Secretary, by posting in a conspicuous place in his office and by such other means as he deems appropriate, the name of any person who within 10 days after the day upon which he is required to perform such acts, has not made (i) reports pursuant to § 967.3, or (ii) payments pursuant to §§ 967.8, 967.9, 967.10, or 967.11;

(7) Submit his books and records to examination by the Secretary and furnish such information and reports as may be requested by the Secretary;

(8) Audit all reports and payments by each handler by inspection of such handler's records and of the records of any other handler or person upon whose utilization the classification of skim milk and butterfat for such handler depends;

(9) Publicly announce, by posting in a conspicuous place in his office and by such other means as he deems appropriate, the price determined for each delivery period as follows:

(i) On or before the 7th day after the end of such delivery period, the minimum class prices and the butterfat differentials for each class pursuant to § 967.5; and

(ii) On or before the 14th day after the end of such delivery period, the uniform price computed pursuant to § 967.7 and the butterfat differential computed pursuant to § 967.8; and

(10) Prepare and disseminate to the public such statistics and information as he deems advisable and as do not reveal confidential information.

By the Dairy Branch, Production and Marketing Administration:

10. Delete the provisions of § 967.3 and substitute therefor the following:

§ 967.3 *Reports, records, and facilities*—(a) *Delivery period reports of receipts and utilization.* On or before the 9th day after the end of each delivery period each handler, except a producer-handler, shall report to the market administrator in the detail and on forms prescribed by the market administrator:

(1) The quantities of butterfat and quantities of skim milk contained in (or used in the production of) all receipts within such delivery period of (i) producer milk, (ii) skim milk and butterfat in any form from any other handler, (iii) emergency milk, and (iv) other source milk; and the sources thereof;

(2) The utilization of all receipts required to be reported under subparagraphs (1) and (2) of this paragraph; and

(3) Such other information with respect to all such receipts and utilization as the market administrator may prescribe.

(b) *Other reports.* (1) Each producer-handler shall make reports to the market administrator at such time and in such manner as the market administrator may prescribe.

(2) On or before the 25th day after the end of each delivery period each handler shall submit to the market administrator such handler's producer pay roll for the preceding delivery period, which shall show (i) the total pounds of milk received from each producer and the total pounds of butterfat contained in such milk, (ii) the amount of payment to each producer and cooperative association, and (iii) the nature and amount of any deductions and charges involved in the payments referred to in subdivision (ii) of this subparagraph.

(c) *Records and facilities.* Each handler shall maintain, and make available to the market administrator or to his representative during the usual hours of business, such accounts and records of his operations and such facilities as are necessary for the market administrator to verify or to establish the correct data with respect to (1) the receipts and utilization, in whatever form, of all skim milk and butterfat received, including milk products received and disposed of in the same form; (2) the weights, samples, and tests for butterfat and for other content of all skim milk and butterfat handled; (3) payments to producers and cooperative associations; and (4) the pounds of skim milk and butterfat contained in or represented by all milk, skim milk, cream and each milk product on hand at the beginning and at the end of each delivery period.

By the Dairy Branch, Production and Marketing Administration:

11. Delete the provisions of § 967.4 and substitute therefor the following:

§ 967.4 *Classification*—(a) *Skim milk and butterfat to be classified.* All skim milk and butterfat, in any form, received within the delivery period by a handler, in producer milk, in emergency milk, in other source milk, and from another handler shall be classified by the market administrator pursuant to the following provisions of this section.

(b) *Classes of utilization.* Subject to the conditions set forth in paragraphs (d) and (e) of this section, the skim milk and butterfat described in paragraph (a) of this section shall be classified by the market administrator on the basis of the following classes:

(1) Class I milk shall be all skim milk and butterfat;

(i) Disposed of in the form of milk or milk drinks, whether plain or flavored, including bulk milk disposed of to bakeries, hotels, restaurants, and other retail food establishments;

(ii) Not specifically accounted for as any item included under subdivision (i) of this subparagraph or as Class II milk, Class III milk, or Class IV milk.

(2) Class II milk shall be all skim milk and butterfat used to produce (i) cream or as any mixture of cream and milk or skim milk (excluding any item accounted for under subparagraph (3) (i) of this paragraph) containing not less than 6 percent of butterfat, or (ii) cottage cheese.

(3) Class III milk shall be all skim milk and butterfat:

(i) Used to produce frozen cream, ice cream, cheese (except cottage cheese), or ice cream mix; or

(ii) Used to produce a milk product other than any of those specified in subparagraph (1) (i), (2), or (4) of this paragraph.

(4) Class IV milk shall be all skim milk and butterfat:

(i) Used to produce butter;
(ii) In actual plant shrinkage of producer milk computed pursuant to paragraph (c) of this section, but not in excess of 3 percent thereof; and
(iii) In actual plant shrinkage of emergency milk and other source milk computed pursuant to paragraph (c) of this section.

(c) *Shrinkage.* The market administrator shall determine the shrinkage of skim milk and butterfat, respectively, in producer milk and in emergency and other source milk in the following manner:

(1) Compute the total shrinkage of skim milk and butterfat, respectively, for each handler; and

(2) Prorate the total shrinkage of skim milk and butterfat, respectively, computed pursuant to subparagraph (1) of this paragraph between producer milk and emergency and other source milk after deducting receipts from other handlers.

(d) *Responsibility of handlers and reclassification of milk.* (1) All skim milk and butterfat shall be Class I milk, unless the handler who first receives such skim milk or butterfat proves to the market administrator that such skim milk or butterfat should be classified otherwise.

(2) Any skim milk or butterfat classified (except that transferred to a producer-handler) in one class shall be reclassified if used or reused by such handler or by another handler in another class.

(e) *Transfers.* Skim milk or butterfat disposed of by a handler either by transfer or diversion shall be classified:

(1) As Class I milk if transferred or diverted in the form of milk or skim milk and as Class II milk if so disposed of in the form of cream to another handler (except a producer-handler) unless utilization in another class is mutually indicated in writing to the market administrator by both handlers on or before the 9th day after the end of the delivery period within which such transaction occurred: *Provided,* That skim milk or butterfat so assigned to a particular class shall be limited to the amount thereof remaining in such class in the plant of the transferee-handler after the subtraction of plant shrinkage pursuant to paragraph (g) of this section, and any excess of such skim milk or butterfat, respectively, shall be assigned in series beginning with the next lowest-priced available utilization;

(2) As Class I milk if transferred or diverted to a producer-handler in the form of milk or skim milk and as Class II milk if so disposed of in the form of cream;

(3) As Class I milk if transferred or diverted in the form of milk and as Class II milk if so disposed of in the form of cream to a nonhandler's plant unless, (i) the handler claims another class on the basis of utilization mutually indicated in writing to the market administrator by both the buyer and seller on or before the 9th day after the end of the delivery period within which such transaction occurred, (ii) the buyer maintains books and records showing the utilization of all skim milk and butterfat at his plant which are made available if requested by the market administrator for the purpose of verification, (iii) such buyer's plant had actually used not less than an equivalent amount of skim milk and butterfat in the use indicated in such statement: *Provided,* That if upon inspection of his records such buyer's plant had not actually used an equivalent amount of skim milk and butterfat in such indicated use, the remaining pounds shall be classified on the basis of the next highest-priced available use in accordance with the classes set forth in paragraph (b) of this section;

(f) *Computation of skim milk and butterfat in each class.* For each delivery period, the market administrator shall correct for mathematical and for other obvious errors the delivery period report submitted by each handler and compute the total pounds of skim milk and butterfat, respectively, in Class I milk, Class II milk, and Class III milk and Class IV milk for such handler.

(g) *Allocation of skim milk and butterfat classified.* (1) The pounds of skim milk remaining in each class after making the following computations shall be the pounds in such class allocated to producer milk:

(i) Subtract plant shrinkage of skim milk pursuant to paragraph (b) (4) (ii) of this section from the total pounds of skim milk in Class IV milk;

(ii) Subtract from the remaining pounds of skim milk in each class the skim milk received from other handlers and assigned pursuant to (e) of this section;

(iii) Subtract pro rata from the pounds of skim milk remaining in each class after making the deduction pursuant to subdivisions (i) and (ii) of this subparagraph the pounds of skim milk in emergency milk;

(iv) Subtract from the remaining pounds of skim milk in each class in series beginning with the lowest-priced available use, the pounds of skim milk contained in milk other than from producers, handlers, and emergency sources; and

(v) Add to the remaining pounds of skim milk in Class IV milk the pounds subtracted pursuant to subdivision (i) of this subparagraph; or if the remaining pounds of skim milk in all classes exceed the pounds of skim milk in producer milk, subtract such excess from the remaining pounds of skim milk in series beginning with the lowest-priced available use.

(2) Allocate classified butterfat to producer milk according to the method prescribed in subparagraph (1) of this paragraph for skim milk.

(3) Determine the weighted average butterfat test of the remaining Class I milk, Class II milk, Class III milk, and Class IV milk computed pursuant to subparagraphs (1) and (2) of this paragraph.

By the Pure Milk Association:

12. Amend § 967.4 (b) (1) to read:

(1) Class I milk shall be all milk disposed of in the form of milk, buttermilk or milk drinks, whether plain or flavored including bulk milk disposed of to bakeries, hotels, restaurants and other retail food establishments, and all milk not accounted for as Class II, Class III, and Class IV milk.

13. Delete the provisions of § 967.4 (d) (7) (ii) and (iii) and substitute therefor the following:

(ii) Subtract from the lowest class in which the handler has milk, the total pounds of milk which were received from sources other than producers and handlers;

(iii) Subtract pro rata from the remaining pounds of milk in each class the pounds of emergency milk received; emergency cream to be deducted pro rata from Class II, Class III, and Class IV milk.

By Reliable Dairy Company, Inc., et al:

14. Delete § 967.4 (b) (1), (2), and (3) and substitute therefor the following:

(b) *Classes of utilization.* Subject to the condition set forth in paragraph (a) of this section, the classes of utilization of milk shall be as follows:

(1) Class I milk shall be all milk disposed of in the form of milk or milk drinks, whether plain or flavored, having a butterfat content of not less than 3.25 percent, and all milk not accounted for as Class II milk, Class III milk, and Class IV milk.

(2) Class II milk shall be all milk, the butterfat from which is disposed of as sweet or sour cream.

(3) Class III milk shall be all milk, the butterfat from which is used to produce a milk product other than one of those specified in Class II or Class IV and including frozen cream, ice cream, cheese, and ice cream mix, and any milk sold as fluid milk and cream to bakery, soup, or candy manufacturing establishments.

15. Amend § 967.4 (b) by adding the following:

(5) Class V milk shall be all milk in excess of the actual and complete requirements of each plant determined as follows: any plant whenever they shall notify the Pure Milk Association or the market administrator not less than 24 hours previous to dispose of all milk above the actual and complete requirements, and said Pure Milk Association or market administrator shall fail to accept delivery of said milk or to dispose of the same and which milk the handler takes into his plant on account of their said failure to accept said delivery or to dispose of said milk.

16. Delete § 967.4 (d) (3) and substitute therefor the following:

(3) Determine the total pounds of milk in Class I as follows: (i) Convert to quarts the quantity of milk disposed of in the form containing not less than 3.25 percent butterfat and multiply by 2.15 and convert to quarts the quantity of flavored milk drinks containing not less than 3.25 percent butterfat and multiply by 1.935 and add the total thus received, (ii) Multiply the result by its average butterfat test, and (iii) If the quantity of butterfat so computed when added to the pounds of butterfat in Class II milk,

Class III milk, and Class IV milk, computed pursuant to subparagraphs (4) (ii), and 6 (ii) of this paragraph, is less than the total pounds of butterfat received, computed in accordance with subparagraph (2) of this paragraph, an amount equal to the difference shall be divided by 4 percent and shall be added to the quantity of milk determined pursuant to subdivision (i) of this subparagraph.

17. Delete § 967.4 (d) (7) and substitute therefor the following:

(7) Determine the classification of milk received from producers as follows:

(i) Subtract from the total pounds of milk in Class IV the total pounds of milk which were received from other handlers;

(ii) Subtract pro rata from the remaining pounds of milk in each class the pounds of supplementary milk received;

(iii) Except as set forth in paragraph (e) of this section, the result shall be known as the "net pool milk" in each class.

18. Delete § 967.4 (e) (2) and substitute therefor the following:

(2) If the total utilization of milk in the various classes for any handler, as computed pursuant to paragraph (d) of this section, is greater than the receipts of milk from producers, the market administrator shall decrease the total pounds of milk in Classes IV, III, II, and in that order for such handler only to the extent that such handler has milk in said respective class by an amount equal to the difference between the receipts of milk from producers, and the total utilization of milk by classes for such handler, provided that from Class IV first shall be deducted the allowable plant shrinkage, which result shall be known as "net pool milk" in each class.

By the Dairy Branch, Production and Marketing Administration:

19. Delete § 967.5 and substitute therefor the following:

§ 967.5 *Minimum prices*—(a) *Basic formula price to be used in determining class prices.* The basic formula price per hundredweight of milk to be used in determining the class prices provided by this section shall be the highest of the prices per hundredweight for milk of 3.5 percent butterfat content determined by the market administrator pursuant to subparagraphs (1), (2), or (3) of this paragraph, computed to the nearest tenth of a cent.

(1) The average of the basic (or field) prices per hundredweight reported to have been paid, or to be paid, for milk of 3.5 percent butterfat content received from farmers during the delivery period at the following plants or places for which prices have been reported to the market administrator or to the Department of Agriculture:

Present Operator and Location

Goshen Milk Condensing Co., Goshen, Ind.
Litchfield Creamery Co., Warsaw, Ind.
New Paris Creamery Co., New Paris, Ind.

Provided, That if one of the above companies fails to report the price for milk so received, the average of the basic (or field) prices per hundredweight reported to have been paid, or to be paid, for milk of 3.5 percent butterfat content received from farmers during the delivery period at the following plants or places for which prices have been reported to the market administrator or the Department of Agriculture shall be used:

Present Operator and Location

Borden Co., Black Creek, Wis.
Borden Co., Greenville, Wis.
Borden Co., Mt. Pleasant, Mich.
Borden Co., New London, Wis.
Borden Co., Orfordville, Wis.
Carnation Co., Berlin, Wis.
Carnation Co., Jefferson, Wis.
Carnation Co., Chilton, Wis.
Carnation Co., Oconomowoc, Wis.
Carnation Co., Richland, Wis.
Carnation Co., Sparta, Mich.
Pet Milk Co., Belleville, Wis.
Pet Milk Co., Coopersville, Mich.
Pet Milk Co., Hudson, Mich.
Pet Milk Co., New Glarus, Wis.
Pet Milk Co., Wayland, Mich.
White House Milk Co., Manitowoc, Wis.
White House Milk Co., West Bend, Wis.

(2) The price per hundredweight computed as follows:

(i) Multiply by six the average daily wholesale price per pound of 92-score butter in the Chicago market as reported by the Department of Agriculture during the delivery period;

(ii) Add an amount equal to 2.4 times the average weekly prevailing price per pound of "Twins" during the delivery period on the Wisconsin Cheese Exchange at Plymouth, Wisconsin: *Provided,* That if the price of "Twins" is not quoted on the Wisconsin Cheese Exchange the weekly prevailing price per pound of "Cheddars" shall be used; and

(iii) Divide by seven, add 30 percent thereof, and then multiply by 3.5.

(3) The price per hundredweight computed by adding together the values pursuant to subdivisions (i) and (ii) of this subparagraph:

(i) Multiply by 3.5 the average daily wholesale price per pound of 92-score butter in the Chicago market, as reported by the Department of Agriculture during the delivery period, add 20 percent; and

(ii) Add or subtract 3.5 cents per hundredweight for each full one-half cent that the arithmetical average of the carlot prices per pound for nonfat dry milk solids (not including that specifically designated animal feed) spray and roller process, f. o. b. manufacturing plants in the Chicago area as published by the Department of Agriculture during the delivery period, is above or below 5.5 cents, except that if such agency does not publish such prices f. o. b. manufacturing plants, there shall be used for the purpose of this computation the arithmetical average of the carlot prices thereof, delivered at Chicago, Illinois, as published weekly by such agency during the delivery period; and in the latter event the figure "7.5" shall be substituted for "5.5" in the above formula.

(b) *Class I milk prices.* Subject to the provisions of paragraphs (f) and (g) of this section, the minimum price per hundredweight, on a 3.5 percent butterfat content basis, to be paid by each handler, at his plant, for producer milk received and classified as Class I milk, shall be the basic formula price determined pursuant to paragraph (a) of this section, plus 65 cents.

(c) *Class II milk prices.* Subject to the provisions of paragraphs (f) and (g) of this section, the minimum price per hundredweight, on a 3.5 percent butterfat content basis, to be paid by each handler, at his plant, for producer milk received and classified as Class II milk, shall be the basic formula price determined pursuant to paragraph (a) of this section, plus 40 cents.

(d) *Class III milk prices.* Subject to the provisions of paragraphs (f) and (g) of this section, the minimum price per hundredweight, on a 3.5 percent butterfat content basis, to be paid by each handler, at his plant, for producer milk received and classified as Class III milk, shall be the same as the basic formula price.

(e) *Class IV milk prices.* Subject to the provisions of paragraphs (f) and (g) of this section the minimum price per hundredweight, on a 3.5 percent butterfat content basis, to be paid by each handler, at his plant, for producer milk received and classified as Class IV milk, shall be the price determined pursuant to paragraph (a) (3) of this section.

(f) *Butterfat differentials to handlers.* If for any handler, the weighted average butterfat test of his classified producer milk is more or less than 3.5 percent, there shall be added to or subtracted from, as the case may be, the price for such class, for each one-tenth of one percent that such weighted average butterfat test is above or below 3.5 percent, a butterfat differential (computed to the nearest tenth of a cent) calculated by the market administrator by multiplying the average daily wholesale price per pound of 92-score butter in the Chicago market as reported by the Department of Agriculture during the delivery period by the following factors for each class respectively and divide the result by 10:

Class I milk—1.35.
Class II milk—1.30.
Class III milk—1.25.
Class IV milk—1.20.

(g) *Emergency price provisions.* Whenever the provisions hereof require the market administrator to use a specific price (or prices) for milk or any milk product for the purpose of determining class prices or for any other purpose, the market administrator shall add to the specified price the amount of any subsidy or other similar payment being made by any Federal agency in connection with the milk, or product, associated with the price specified: *Provided,* That if for any reason the price specified is not reported or published as indicated, the market administrator shall use the applicable maximum uniform price established by regulations of any Federal agency plus the amount of any subsidy or other similar payment: *Provided further,* That if the specified price is not reported or published and there is no applicable maximum uniform price, or if the specified price is not reported or published and the Secretary determines that the market price is below the applicable maximum uniform price, the market admin-

istrator shall use a price determined by the Secretary to be equivalent to or comparable with the price specified.

By the Pure Milk Association:

20. Amend § 967.5 (a) (1), (2), and (3) to read:

(1) *Class I milk.* The price per hundredweight for Class I milk shall be the price determined pursuant to paragraph (b) of this section, plus:

For the delivery periods of:	
January through April	$0.70
May and June	.50
July and August	.70
September through December	1.00

(2) *Class II milk.* The price per hundredweight for Class II milk shall be the price determined pursuant to paragraph (b) of this section, plus:

For the delivery periods of:	
January through August	$0.37
September through December	.68

(3) *Class III milk.* The price per hundredweight for Class III milk shall be the average as computed by the market administrator of the prices ascertained to have been paid for milk of 4 percent butterfat content received during the delivery period at:

Goshen Milk Condensing Co., Goshen, Ind.;
Litchfield Creamery Co., Warsaw, Ind.; and
New Paris Creamery Co., New Paris, Ind.;

or the average price as computed by the market administrator for milk of 4 percent butterfat content received during the delivery period at the following places, i. e.,

Borden Co., Black Creek, Wis.
Borden Co., Greenville, Wis.
Borden Co., Mt. Pleasant, Mich.
Borden Co., New London, Wis.
Borden Co., Orfordville, Wis.
Carnation Co., Berlin, Wis.
Carnation Co., Jefferson, Wis.
Carnation Co., Chilton, Wis.
Carnation Co., Oconomowoc, Wis.
Carnation Co., Richland, Wis.
Carnation Co., Sparta, Mich.
Pet Milk Co., Belleville, Wis.
Pet Milk Co., Coopersville, Mich.
Pet Milk Co., Hudson, Mich.
Pet Milk Co., New Glarus, Wis.
Pet Milk Co., Wayland, Mich.
White House Milk Co., Manitowoc, Wis.
White House Milk Co., West Bend, Wis.

or the price computed under subparagraph (4) of this paragraph, whichever is the highest.

21. Delete from § 967.5 (a) (4) the figure "3½" and substitute therefor "3¾"; the figures "5½" and substitute therefor "5"; and the figure "7½" and substitute therefor "6½."

By Reliable Dairy Company, Inc., et al.:

22. Delete § 967.5 (a) (3) and substitute therefor the following:

(3) The price per hundredweight for Class III milk shall be the average, as computed by the market administrator, of the basic (or field) prices ascertained to have been paid for milk of 4 percent butterfat content received during the delivery period at the following places for which prices are reported to the market administrator by the three listed companies or by the United States Department of Agriculture (or by such other Federal agency as may hereafter be authorized to perform this price reporting function):

Concern and Location

Goshen Milk Condensing Co., Goshen, Ind.
Litchfield Creamery Co., Warsaw, Ind.
New Paris Creamery Co., New Paris, Ind.

Provided, That if any one of the above companies fails to report the price of milk so received, the price per hundredweight for Class III milk shall be the average, as computed by the market administrator ascertained to have been paid by any two of the above-named companies.

23. Amend § 967.5 (a) by adding a new subparagraph as follows:

(5) *Class V milk.* The price of Class V milk shall be the net price actually received less 20 cents per hundredweight, as and for a handling charge, f. o. b. the handler's plant.

24. Delete § 967.5 (b).

25. Delete § 967.5 (d).

26. Amend § 967.5 by adding a new paragraph (e) as follows:

(e) *Sales outside the marketing area.* The price to be paid by a handler for milk disposed of outside the marketing area, in lieu of the price otherwise applicable pursuant to this section shall be the price, as ascertained by the market administrator, which is being paid for milk of equivalent use in the market where such milk is disposed of.

27. Amend § 967.5 by adding a new paragraph (f) as follows:

(f) *Degraded milk.* Whenever the duly constituted authorities find that any producer is not producing the highest quality milk for sale in accordance with regulations for the sale of fluid milk in the marketing area, or any part thereof, then said producer shall be paid a sum as herein provided less 20 cents per hundredweight so long as he is not producing milk in said highest quality.

By the Dairy Branch, Production and Marketing Administration:

28. Delete the provisions of § 967.6 and substitute therefor the following:

§ 967.6 *Application of provisions—*(a) *Payment for milk received from sources determined as other than producers or other handlers.* If any handler uses skim milk and butterfat from sources other than producers or other handlers, such handler shall pay producers, through the producer settlement fund, the difference between the value of such skim milk and butterfat at the Class IV price and the value of such milk in accordance with its classification pursuant to § 967.4 (g).

(b) *Exempt milk.* Milk received by a handler the handling of which the Secretary determines to be subject to the pricing and payment provisions of any other Federal milk marketing agreement or order issued pursuant to the act for any fluid milk marketing area shall not be subject to the pricing and payment provisions of this section.

(c) *Diverted milk.* Producer milk diverted from a handler's plant to a nonhandler's plant shall be deemed to have been received by the handler on whose account such milk was diverted.

(d) *Producer-handler.* Sections 967.4, 967.5, 967.7, 967.8, 967.9, and 967.10 shall not apply to a producer-handler in his capacity as a handler.

By the Dairy Branch, Production and Marketing Administration:

29. Delete the provisions of § 967.7 and substitute therefor the following:

§ 967.7 *Determination of uniform prices—*(a) *Computation of value of milk.* Subject to the provisions of § 967.6 (a), the value of producer milk received during each delivery period by each handler shall be a sum of money computed by the market administrator by multiplying the pounds of such milk in each class for the delivery period, by the applicable class prices, and adding together the resulting amounts: *Provided,* That if a handler, after subtracting other source milk, emergency milk, and receipts from other handlers, has disposed of skim milk or butterfat in excess of the skim milk or butterfat which, on the basis of his report for the delivery period pursuant to § 967.3 (a), has been credited to producers as having been received from them, there shall be added an amount computed by multiplying the pounds in each class as subtracted pursuant to § 967.4 (g) (1) (v) and (2) by the applicable class prices.

(b) *Computation of uniform price.* For each delivery period, the market administrator shall compute the "uniform price" per hundredweight for milk of 3.5 percent butterfat content received from producers as follows:

(1) Combine into one total the values computed pursuant to paragraph (a) of this section for all handlers who made the reports prescribed by § 967.3; except those in default of the payments prescribed in § 967.8 (a) for the preceding delivery period;

(2) Add an amount representing the cash balance on hand in the producer-settlement fund, less the total amount of contingent obligations to handlers pursuant to § 967.8 (e);

(3) Subtract, if the weighted average butterfat test of producer milk represented by the values included under subparagraph (1) of this paragraph is greater than 3.5 percent, or add, if such butterfat test is less than 3.5 percent, an amount computed by: Multiplying the amount by which its weighted average butterfat test varies from 3.5 percent by the butterfat differential computed pursuant to § 967.8 (b), and multiplying the resulting figure by the total hundredweight of such milk;

(4) Divide the resulting amount by the total hundredweight of producer milk represented by the values included in subparagraph (1) of this paragraph; and

(5) Subtract not less than 4 cents nor more than 5 cents (adjusting to the nearest one-tenth cent) from the amount per hundredweight computed under subparagraph (4) of this paragraph.

(c) *Notification of handlers.* On or before the 15th day after the end of each delivery period, the market administrator shall mail to each handler at his last known address, a statement showing

(1) the amount and value of his milk in each class and the totals thereof; (2) the applicable minimum class prices and uniform prices; (3) the amount due such handler or the amount to be paid by such handler, as the case may be, pursuant to § 967.8 (d) and (e); and (4) the amount to be paid by each handler pursuant to §§ 967.8 (a), 967.9, and 967.10.

By the Pure Milk Association:

30. Amend § 967.7 (b) by adding thereto:

(5) add 20 cents per hundredweight on all degraded milk.

By Reliable Dairy Company, Inc., et al.

31. Delete § 967.7 (b) (1) and substitute therefor the following:

(1) Combine into one total the net pool obligations of all handlers, computed pursuant to paragraph (a) of this section, who made the reports pursuant to § 967.3 (a) (1) for such delivery period and the payments required by § 967.8 (d) for the delivery period immediately preceding; subtract for each of the delivery periods of April, May, June and an amount representing 25 cents per hundredweight of milk received from producers by the handlers whose milk values are included in this paragraph.

By the Dairy Branch, Production and Marketing Administration:

32. Delete § 967.8 and substitute therefor the following:

§ 967.8 *Payment for milk*—(a) *Time and method of final payment.* Each handler shall make payments as follows:

(1) On or before the 19th day after the end of each delivery period, to each producer, except producers for whom payment is received from the handler by a cooperative association pursuant to subparagraph (2) of this paragraph, at not less than the uniform price for such delivery period pursuant to § 967.7 (b) adjusted by the producer butterfat differential pursuant to paragraph (b) of this section, for all milk received from such producer during such delivery period: *Provided,* That if by such date such handler has not received full payment for such delivery period pursuant to paragraph (e) of this section, he may reduce such payments uniformly per hundredweight for all producers by an amount not in excess of the per hundredweight reduction in payment from the market administrator; however, the handler shall make such balance of payment to those producers to whom it is due on or before the date for making payments pursuant to this paragraph next following that on which such balance of payment is received from the market administrator.

(2) On or before the 16th day after the end of each delivery period, to a cooperative association with respect to milk caused to be delivered from producers' farms to such handler by such association during such delivery period, not less than the value of such milk computed at the minimum class prices provided by § 967.5. For the purpose of determining the classification of milk caused to be so delivered by a cooperative association to a handler, such milk shall be ratably apportioned among the receiving handler's total Class I milk, Class II milk, Class III milk, and Class IV milk as determined pursuant to § 967.4 (g).

(b) *Producer butterfat differential.* In making payments pursuant to paragraph (a) (1) of this section there shall be added to, or subtracted from, the uniform price for milk of 3.5 percent butterfat content, for each one-tenth of one percent of butterfat content in such producer milk above or below 3.5 percent, as the case may be, an amount computed by multiplying the average daily wholesale price per pound of 92-score butter at Chicago, as reported by the Department of Agriculture for the delivery period, by 1.20, dividing by 10, and rounding to the nearest tenth of a cent.

(c) *Producer-settlement fund.* The market administrator shall establish and maintain a separate fund known as the "producer-settlement fund" into which he shall deposit all payments made by handlers pursuant to paragraph (d) of this section and out of which he shall make all payments to handlers pursuant to paragraph (e) of this section.

(d) *Payments to the producer-settlement fund.* On or before the 17th day after the end of each delivery period, each handler shall pay to the market administrator the amount by which the utilization value of producer milk received by such handler during such delivery period is greater than the value of such milk computed at the uniform price pursuant to § 967.7 (b) adjusted by the butterfat differential provided by paragraph (c) of this section: *Provided,* That with respect to milk for which payment is made by a handler to a cooperative association pursuant to paragraph (a) (2) of this section, the association, in turn, shall pay to the market administrator, on or before the 17th day after the end of each delivery period, the amount by which the utilization value of such milk is greater than its value computed at the uniform price pursuant to § 967.7 (b) adjusted by the butterfat differential provided by paragraph (b) of this section.

(e) *Payments out of the producer-settlement fund.* On or before the 18th day after the end of each delivery period, the market administrator shall pay to each handler the amount by which the utilization value of producer milk received by such handler during such delivery period is less than the value of such milk computed at the uniform price pursuant to § 967.7 (b) adjusted by the butterfat differential provided by paragraph (b) of this section, less any unpaid obligations of such handler to the market administrator pursuant to paragraph (d) of this section, §§ 967.9, 967.10, and 967.11: *Provided,* That with respect to milk for which payment is made by a handler to a cooperative association pursuant to paragraph (a) (2) of this section, the market administrator shall pay, on or before the 18th day after the end of each delivery period, to such association the amount by which the utilization value of such milk is less than its value computed at the uniform price pursuant to § 967.7 (b) adjusted by the butterfat differential provided by paragraph (b) of this section: *And provided further,* That if the balance in the producer-settlement fund is insufficient to make all payments pursuant to this paragraph, the market administrator shall reduce uniformly such payments and shall complete such payments as soon as the necessary funds are available.

By the Pure Milk Association:

33. Delete the period at the end of § 967.8 (a) and add thereto the following: "less 20 cents per hundredweight on all degraded milk."

By Reliable Dairy Company, Inc., et al:

34. Delete § 967.8 (e) and substitute therefor the following:

(e) *Payments out of the producer-settlement fund.* (1) On or before the 18th day after the end of each delivery period, the market administrator shall pay to each handler the pool credit balance shown on the account rendered pursuant to paragraph (c) of this section for such delivery period, less any unpaid obligation of the handler. If at such time the balance in the producer-settlement fund is insufficient to make all payments pursuant to this paragraph, the market administrator shall reduce uniformly such payments, and shall complete such payments as soon as the necessary funds are available. No handler who, on the 18th day after the end of each delivery period, has not received the balance of the payment due him from the market administrator shall be deemed to be in violation of paragraph (a) of this section if he reduces his total payments uniformly to all producers by not more than the amount of the reduction in payment from the producer-settlement fund.

(2) On or before the 15th day after the end of each of the delivery periods of September, October, and November, the market administrator shall pay out of the producer-settlement fund to each producer an amount computed as follows: divide ⅓ of the aggregate amount held pursuant to § 967.7 (b) (1) by the hundredweight of producer's milk delivered during the delivery period involved (September, October, or November as above) and apply the resulting amount per hundredweight to the milk of each producer for such delivery period.

By the Dairy Branch, Production and Marketing Administration:

35. Delete § 967.9 and substitute therefor the following:

§ 967.9 *Expense of administration.* As his pro rata share of the expense incurred pursuant to § 967.2 (c) (4) each handler shall pay the market administrator, on or before the 17th day after the end of each delivery period, 4 cents per hundredweight, or such lesser amount as the Secretary from time to time may prescribe with respect to all milk received within the delivery period from producers (including such handler's own production) and from sources other than producers or other handlers.

By Reliable Dairy Company, Inc., et al.:

36. Amend § 967.9 by deleting from lines 9 and 10 of this section, the words "and from his own production."

By the Dairy Branch, Production and Marketing Administration:

37. Delete § 967.10 and substitute therefor the following:

§ 967.10 *Marketing services*—(a) *Marketing service deductions.* Except as set forth in paragraph (b) of this section, each handler, in making payments to producers pursuant to § 967.8 (a) (1), shall make a deduction of 3 cents per hundredweight of milk, or such lesser deduction as the Secretary from time to time may prescribe, with respect to the following:

(1) All milk received from producers at a plant not operated by a cooperative association; and

(2) All milk received at a plant operated by a cooperative association from producers who are not members of such association.

Such deductions shall be paid by the handler to the market administrator on or before the 17th day after the end of each delivery period. Such moneys shall be expended by the market administrator for verification of weights, samples, and tests of milk received from such producers and in providing for market information to such producers, such services to be performed in whole or in part by the market administrator or by an agent engaged by and responsible to him.

(b) *Marketing service deduction with respect to members of, or producers marketing through, a cooperative association.* In the case of each producer (1) who is a member of, or who has given written authorization for the rendering of marketing services and the taking of deduction therefor to a cooperative association, (2) whose milk is received at a plant not operated by such association, and (3) for whom the Secretary determines that such association is performing the services described in paragraph (a) of this section, each handler shall deduct, in lieu of the deduction specified under paragraph (a) of this section, from the payments made pursuant to § 932.8 (a) (1) the amount per hundredweight on milk authorized by such producer and shall pay over, on or before the 17th day after the end of such delivery period, such deduction to the association entitled to receive it under this paragraph.

By Reliable Dairy Company, Inc., et al:

38. Amend § 967.10 (a) by inserting "excepting such handler's own production" at the end of the first sentence of said section, and by adding the following words at the end of the second sentence of said section: "*Provided,* That the market administrator may make a reasonable charge for any verification or test of any handler's own production."

By the Dairy Branch, Production and Marketing Administration:

39. Delete §§ 967.11 and 967.12 and substitute therefor the following:

§ 967.11 *Adjustments of accounts*—(a) *Errors in payments.* Whenever audit by the market administrator of any handler's reports, books, records, or accounts discloses errors resulting in moneys due (1) the market administrator from such handler, (2) such handler from the market administrator, or (3) any producer or cooperative association from such handler, the market administrator shall promptly notify such handler of any such amount due; and payment thereof shall be made on or before the next date for making payment set forth in the provision under which such error occurred following the 5th day after such notice.

(b) *Interest on overdue accounts.* Any unpaid obligation of a handler or of the market administrator pursuant to §§ 967.8, 967.9, 967.10, or paragraph (a) of this section shall bear interest at the rate of one-half of one percent per month, such interest to accrue on the 1st day of the calendar month next following the due date of such obligation and on the first day of each calendar month thereafter until such obligation is paid.

§ 967.12 *Effective time.* The provisions hereof, or of any amendment hereto, shall become effective at such time as the Secretary may declare and shall continue in force until suspended or terminated.

§ 967.13 *Suspension or termination*—(a) *When suspended or terminated.* The Secretary shall, whenever he finds that this order, or any provision thereof, obstructs or does not tend to effectuate the declared policy of the act, terminate or suspend the operation of this order or any such provision thereof.

(b) *Continuing obligations.* If, upon the suspension or termination of any or all provisions of this order, there are any obligations thereunder the final accrual or ascertainment of which requires further acts by any person (including the market administrator), such further acts shall be performed notwithstanding such suspension or termination.

(c) *Liquidation.* Upon the suspension or termination of the provisions hereof, except this section, the market administrator, or such other liquidating agent as the Secretary may designate, shall, if so directed by the Secretary, liquidate the business of the market administrator's office, dispose of all property in his possession or control, including accounts receivable, and execute and deliver all assignments or other instruments necessary or appropriate to effectuate any such disposition. If a liquidating agent is so designated, all assets, books, and records of the market administrator shall be transferred promptly to such liquidating agent. If, upon such liquidation, the funds on hand exceed the amounts required to pay outstanding obligations of the office of the market administrator and to pay necessary expenses of liquidation and distribution, such excess shall be distributed to contributing handlers and producers in an equitable manner.

§ 967.14 *Agents.* The Secretary may, by designation in writing, name any officer or employe of the United States to act as his agent or representative in connection with any of the provisions hereof.

§ 967.15 *Separability of provisions.* If any provision hereof, or its application to any person or circumstances, is held invalid, the application of such provision, and of the remaining provisions hereof, to other persons or circumstances shall not be affected thereby.

40. Delete § 967.13.

By Reliable Dairy Company, Inc., et al.:

41. Amend § 967.11 by adding a new paragraph as follows:

(e) *Termination for lack of supply.* Whenever the Pure Milk Association or the Market Administrator cannot furnish the minimum requirements of milk required by any plant for a period of 30 days as shown upon the reports to the market administrator and that during said 30 days any such plant is required to purchase supplementary milk then this order shall automatically terminate.

General proposals by the Dairy Branch, Production and Marketing Administration:

42. Make such other changes as may be required to make the entire tentatively approved marketing agreement and the marketing order, as amended, conform with any amendments thereto which may result from this hearing.

Copies of this notice of hearing and of the tentatively approved marketing agreement and order, as amended, now in effect, may be procured from the market administrator, 116 South William Street, South Bend 24, Indiana, or from the Hearing Clerk, Room 0306, South Building, Washington 25, D. C., or may be there inspected.

Dated: March 31, 1947.

[SEAL] E. A. MEYER,
Assistant Administrator.

[F. R. Doc. 47-3239; Filed, Apr. 3, 1947; 8:45 a. m.]

SECURITIES AND EXCHANGE COMMISSION

[17 CFR, Parts 230, 239]

REGISTRATION AND REGISTRATION PROCEDURE

NOTICE OF PROPOSED LEGISLATION

Notice is hereby given that the Securities and Exchange Commission has under consideration a proposal for the revision of the rules comprising Regulation C pursuant to the Securities Act of 1933, particularly sections 6, 7, 8, 10 and 19 (a) thereof. The proposed revision is set forth below.

Regulation C is the portion of the general rules and regulations under the act dealing with registration and registration procedure. The purpose of the proposed revision is twofold. First, it would eliminate a great deal of obsolete material, and second, it would reorganize the remaining rules in a manner intended to facilitate the registration of securities according to the simplified procedure provided by the Commission's recently revised Form S-1 (17 CFR 239.11, 11 F. R. 177A-732).

Persons desiring to comment on the proposed revision may obtain copies thereof from the principal office of the Commission at the address indicated below.

All interested persons may submit data, views and comments in writing to the Securities and Exchange Commission at its principal office, 18th and Locust Streets, Philadelphia 3, Pennsylvania, on or before April 21, 1947.

REGULATION C—REGISTRATION

§ 230.400 *Application of Regulation C.* The rules contained in §§ 230.400 to 230.492 shall govern every registration of securities under the act, except that any provision in a form covering the same subject matter as any such rule shall be controlling.

GENERAL REQUIREMENTS

§ 230.401 *Requirement as to proper form.* A registration statement shall be prepared in accordance with the form prescribed therefor by the Commission as in effect on the date of filing. Any registration statement shall be deemed to be filed on the proper form unless objection to the form is made by the Commission prior to the effective date of the statement.

§ 230.402 *Number of copies; signatures; binding.* (a) Three copies of the complete registration statement, including exhibits and all other papers and documents filed as a part of the statement, shall be filed with the Commission. At least the original of every statement filed with the principal office of the Commission, and at least the original and one copy of every statement filed with a regional office pursuant to §230.455 (b) shall be signed by the persons specified in section 6 (a) of the act.

(b) Each copy of the registration statement filed with the Commission shall be bound in one or more parts, without stiff covers. The binding shall be made on the left-hand side and in such manners as to leave the reading matter legible.

§ 230.403 *Requirements as to paper and printing.* (a) Registration statements shall be filed on good quality, unglazed, white paper 8½ x 13 inches in size, insofar as practicable. However, tables, charts, maps, and financial statements may be on larger paper if folded to that size, and the prospectus may be on smaller paper if the registrant so desires.

(b) All papers and documents filed as a part of a registration statement shall, insofar as practicable, be printed, mimeographed or typewritten. All such material shall be clear, easily readable, and suitable for repeated photocopying.

(c) All printing, mimeographing, typing or other markings shall be in black ink, except that debits in credit categories and credits in debit categories may be set forth in red or black ink, but shall in all cases be designated in such manner as to be clearly distinguishable as such on photocopies.

§ 230.404 *Preparation of registration statement.* (a) Notwithstanding any requirement of the appropriate form to the contrary, a copy of the proposed prospectus may be filed as a part of the registration statement proper in lieu of furnishing the information in item-and-answer form. Wherever this procedure is followed, either pursuant to this section or otherwise, the text of the items of the form are to be omitted from the registration statement, as well as from the prospectus, except to the extent provided in paragraph (b) of this section. All instructions to items of the form and instructions as to financial statements, exhibits, or prospectuses are to be omitted from the registration statement in all cases.

(b) Where any items of the form require information not required to be included in the prospectus, the text of such items, together with the answers thereto, and any financial statements not required to be included in the prospectus shall be filed with the prospectus under cover of the facing sheet of the form as a part of the registration statement proper.

(c) Every registration statement shall include a cross reference sheet showing the location in the prospectus of the information required to be included in the prospectus in response to the items of the form. If any item of the form is inapplicable, or the answer thereto is in the negative and is omitted from the prospectus, a statement to that effect shall be made in the cross reference sheet. The cross reference sheet is to be inserted in the registration statement immediately following the facing sheet.

§ 230.405 *Definitions of terms used in the forms.* Unless the context otherwise requires, all terms used in the forms for registration have the same meanings as in the act and in the general rules and regulations. In addition, the following definitions apply, unless the context otherwise requires:

Affiliate. An "affiliate" of, or a person "affiliated" with, a specified person, is a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the person specified.

Amount. The term "amount", when used in regard to securities, means the principal amount if relating to evidences of indebtedness, the number of shares if relating to shares, and the number of units if relating to any other kind of security.

Certified. The term "certified", when used in regard to financial statements, means certified by an independent public or independent certified public accountant or accountants.

Charter. The term "charter" includes articles of incorporation, declarations of trust, articles of association or partnership, or any similar instrument, as amended, effecting (either with or without filing with any governmental agency) the organization or creation of an incorporated or unincorporated person.

Commission. The term "Commission" means the Securities and Exchange Commission.

Control. The term "control" (including the terms "controlling", "controlled by" and "under common control with") means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract, or otherwise.

Director. The terms "director", "principal executive, financial and accounting officer", and "trustee", or any other words indicating the holder of a position or office, include persons, by whatever titles designated, whose duties are those ordinarily performed by holders of such positions or offices.

Employee. The term "employee" means a person other than a director, trustee, or officer.

Equity security. The term "equity security" means any stock or similar security; or any security convertible, with or without consideration, into such a security, or carrying any warrant or right to subscribe to or purchase such a security; or any such warrant or right.

Fiscal year. The term "fiscal year" means the annual accounting period or, if no closing date has been adopted, the calendar year ending on December 31.

Funded debt. The term "funded debt" has reference to any indebtedness having a maturity at the time of its creation of more than one year, independent of acceleration.

Majority-owned subsidiary. The term "majority-owned subsidiary" means a subsidiary of which securities representing in the aggregate more than fifty percent of the voting power are owned directly by its parent and/or one or more of the parent's other majority-owned subsidiaries.

Material. The term "material", when used to qualify a requirement for the furnishing of information as to any subject, limits the information required to those matters as to which an average prudent investor ought reasonably to be informed before purchasing the security registered.

Parent. A "parent" of a specified person is an affiliate controlling such person directly, or indirectly through one or more intermediaries.

Predecessor. The term "predecessor" means a person the major portion of the business and assets of which another person acquired in a single succession, or in a series of successions in each of which the acquiring person acquired the major portion of the business and assets of the acquired person.

Principal underwriter. The term "principal underwriter" means an underwriter in privity of contract with the issuer of the securities as to which he is underwriter, the term "issuer" having the meaning given in sections 2 (4) and 2 (11) of the act.

Promoter. The term "promoter" includes:

(a) Any person who, acting alone or in conjunction with one or more other persons, directly or indirectly takes initiative in founding and organizing the business or enterprise of an issuer;

(b) Any person who, in connection with the founding and organizing of the business or enterprise of an issuer, directly or indirectly receives in consideration of services or property, or both services and property, 10 percent or more of any class of securities of the issuer or 10 percent or more of the proceeds from the sale of any class of securities. However, a person who receives such securities or proceeds either solely as underwriting commissions or solely in consideration of property shall not be deemed a promoter within the meaning of this paragraph if such person does not otherwise take part in founding and organizing the enterprise.

Registrant. The term "registrant" means the issuer of the securities for which the registration statement is filed.

Share. The term "share" means a share of stock in a corporation or unit of interest in an unincorporated person.

Significant subsidiary. The term "significant subsidiary" means a subsidiary meeting any one of the following conditions:

(a) The investments in and advances to the subsidiary on the part of its parent and the parent's other subsidiaries exceed 5 percent of the assets of the parent as shown by its most recent individual balance sheet being filed.

(b) The assets of the subsidiary exceed 5 percent of (1) the assets of its parent and the parent's subsidiaries as shown by the most recent consolidated balance sheet being filed, or (2) if a consolidated balance sheet is not being filed, the assets of the parent as shown by its most recent balance sheet being filed.

(c) The sales and operating revenues of the subsidiary exceed 5 percent of (1) the sales and operating revenues of its parent and the parent's subsidiaries as shown by the consolidated profit and loss statement being filed for the most recent fiscal year, or (2) if a consolidated profit and loss statement is not being filed, the sales and operating revenues of the parent as shown by its profit and loss statement being filed for the most recent fiscal year.

(d) The subsidiary is the parent of one or more subsidiaries and together with such subsidiaries would, if considered in the aggregate, constitute a significant subsidiary.

Subsidiary. A "subsidiary" of a specified person is an affiliate controlled by such person directly, or indirectly through one or more intermediaries. (See also "majority-owned subsidiary," "significant subsidiary," and "totally-held subsidiary.")

Succession. The term "succession" means the direct acquisition of the assets comprising a going business, whether by merger, consolidation, purchase, or other direct transfer. The terms does not include the acquisition of control of a business unless followed by the direct acquisition of its assets. The terms "succeed" and "successor" have meanings correlative to the foregoing.

Totally-held subsidiary. The term "totally-held subsidiary" means a subsidiary (a) substantially all of the outstanding securities of which are owned by its parent and/or the parent's other totally-held subsidiaries, and (b) which does not owe to any person other than its parent and/or the parent's other totally-held subsidiaries any debt of an amount which is material in relation to the particular subsidiary: *Provided,* That the existence of any indebtedness incurred in the ordinary course of business which is not overdue and which matures within one year from the date of its creation, whether evidenced by securities or not, shall not prevent a subsidiary from being deemed a totally-held subsidiary.

Voting power. The term "voting power" means the right, other than as affected by events of default, to vote or, by virtue of beneficial ownership of securities or otherwise, to direct votes for the election of directors.

§ 230.406 *Title of securities.* Wherever the title of securities is required to be stated there shall be given such information as will indicate the type and general character of the securities, including the following:

(a) In the case of shares, the par or stated value, if any; the rate of dividends, if fixed, and whether cumulative or noncumulative; the preference, if any; and if convertible, a statement to that effect.

(b) In the case of funded debt, the rate of interest; the date of maturity, or if the issue matures serially, a brief indication of the serial maturities, such as "maturing serially from 1950 to 1960"; if the payment of principal or interest is contingent, an appropriate indication of such contingency; the priority of the issue; and if convertible, a statement to that effect.

(c) In the case of any other kind of security, appropriate information of comparable character.

§ 230.407 *Interpretation of requirements.* Unless the context clearly shows otherwise:

(a) The forms and instructions require information only as to the registrant.

(b) Whenever any fixed period of time in the past is indicated, such period shall be computed from the date of filing the registration statement, as determined by sections 6 (c) and 8 (a) of the act and the rules and regulations thereunder.

(c) Whenever words relate to the future, they have reference solely to present intention.

§ 230.408 *Additional information.* The information required by the rules and the appropriate form to be included in a registration statement shall be furnished as a minimum requirement to which there shall be added any further material information necessary to make the required statements, in the light of the circumstances under which they are made, not misleading.

§ 230.409 *Information unknown or not reasonably available.* Information required need be given only insofar as it is known or reasonably available to the registrant. If any required information is unknown and not reasonably available to the registrant, either because the obtaining thereof would involve unreasonable effort or expense, or because it rests peculiarly within the knowledge of another person not affiliated with the registrant, the information may be omitted, subject to the following conditions:

(a) The registrant shall give such information on the subject as it possesses or can acquire without unreasonable effort or expense, together with the sources thereof, and may include a disclaimer of responsibility for the accuracy or completeness thereof.

(b) The registrant shall include a statement either showing that unreasonable effort or expense would be involved or indicating the absence of any affiliation with the person within whose knowledge the information rests and stating the result of a request made to such person for the information.

§ 230.410 *Disclaimer of control.* If the existence of control is open to reasonable doubt in any instance, the registrant may disclaim the existence of control and any admission thereof; in such case, however, the registrant shall state the material facts pertinent to the possible existence of control.

§ 230.411 *Incorporation of financial statements by reference.* Subject to § 230.448 any financial statement or part thereof previously or concurrently filed with any office of the Commission pursuant to any Act administered by the Commission may be incorporated by reference in any registration statement filed with any office of the Commission, if it substantially conforms to the requirements of the appropriate form and is not required to be included in the prospectus.

§ 230.412 *Registration of additional securities.* The registration of additional securities of the same class as other securities for which a registration statement is already in effect shall be effected through a separate registration statement relating to the additional securities.

FORM AND CONTENT OF PROSPECTUSES

§ 230.420 *Legibility of prospectuses.* The body of all printed prospectuses other than newspaper prospectuses shall be in type at least as legible as ten point leaded type.

§ 230.421 *Presentation of information in prospectuses.* (a) The information required in a prospectus need not follow the order of the items or other requirements in the form. Such information shall not, however, be set forth in such fashion as to obscure any of the required information or any information necessary to keep the required information from being incomplete or misleading. Where an item requires information to be given in a prospectus in tabular form it shall be given in substantially the tabular form specified in the item.

(b) All information contained in a prospectus shall be set forth under appropriate captions or headings reasonably indicative of the subject matter set forth thereunder. Except as to financial statements and other tabular data, all information set forth in a prospectus shall be divided into reasonably short paragraphs or sections.

(c) Every prospectus shall include in the forepart thereof a reasonably detailed table of contents showing the subject matter of the various sections or subdivisions of the prospectus and the page number on which each such section or subdivision begins.

(d) All information required to be included in a prospectus shall be clearly understandable without the necessity of referring to the particular form or to the general rules and regulations. Except as to financial statements and information required in tabular form, the information set forth in a prospectus may be expressed in condensed or summarized form. Financial statements included in

a prospectus are to be set forth in comparative form if practicable, and shall include the notes thereto and the accountants' certificate.

§ 230.422 *Summaries or outlines of documents.* Where a summary or outline of the provisions of any document is required, only a brief statement shall be made, in succinct and condensed form, as to the most important provisions of the document. In addition to such statement, the summary or outline may, subject to § 230.448, incorporate by reference particular items, sections, or paragraphs of any exhibit and may be qualified in its entirety by such reference. Matter contained in an exhibit may be incorporated by reference in a prospectus only to the extent permitted by this section.

§ 230.423 *Date of prospectuses.* Each prospectus used upon the commencement of the public offering of registered securities shall be dated as of the effective date of the registration statement. Each revised, amended or supplemented prospectus used thereafter shall bear the approximate date of its issuance, in addition to the date required by the preceding sentence.

§ 230.424 *Filing of prospectuses; number of copies.* (a) In addition to the three copies of the prospectus included in the body of the registration statement proper, five copies of the prospectus proposed to be used upon the commencement of the public offering of a security shall be filed with the registration statement at the time the statement is filed. A copy of the cross reference sheet required by § 230.404 (c) shall be bound with or attached to each copy of the prospectus so filed.

(b) Within five days after the commencement of the public offering, twenty copies of each form of prospectus used in connection with such offering shall be filed, in the exact form used, with the office of the Commission with which the registration statement was filed.

(c) No prospectus which purports to comply with section 10 of the act and which varies from any form of prospectus filed pursuant to paragraph (b) of this section shall be used until twenty copies thereof shall have been filed with the office of the Commission with which the registration statement was filed.

(d) Every prospectus consisting of a radio broadcast shall be reduced to writing. At least five days before the prospectus is broadcast or otherwise issued to the public, five copies thereof shall be filed with the office of the Commission with which the registration statement was filed.

§ 230.425 *Statement required in all prospectuses.* There shall be placed on the front page of every prospectus, in conspicuous print, the following three paragraphs, with the first and third paragraphs in capital letters:

THESE SECURITIES HAVE NOT BEEN APPROVED OR DISAPPROVED BY THE SECURITIES AND EXCHANGE COMMISSION.

---------- (INSERT NAME OF ISSUER) HAS REGISTERED THE SECURITIES BY FILING CERTAIN INFORMATION WITH THE COMMISSION. THE COMMISSION DOES NOT PASS UPON THE MERITS OF ANY SECURITIES REGISTERED WITH IT.

IT IS A CRIMINAL OFFENSE TO REPRESENT THAT THE COMMISSION HAS APPROVED THESE SECURITIES OR HAS MADE ANY FINDINGS THAT THE STATEMENTS IN THIS PROSPECTUS OR IN THE REGISTRATION STATEMENT ARE CORRECT.

§ 230.426 *Statement as to stabilizing.* In any case in which the registrant or any of the underwriters knows or has reasonable grounds to believe that it is intended to stabilize the price of any security to facilitate the offering of the registered security, there shall be placed on the first or second page of every prospectus the following statement in capital letters:

TO FACILITATE THE OFFERING, IT IS INTENDED TO STABILIZE THE PRICE(S) OF ---------- (TITLE OF SECURITIES) ON ----------. (NAME EACH EXCHANGE. IF NONE, OMIT THIS LINE.)

THIS STATEMENT IS NOT AN ASSURANCE THAT THE PRICE(S) OF THE ABOVE SECURITIES WILL BE STABILIZED OR THAT THE STABILIZING, IF COMMENCED, MAY NOT BE DISCONTINUED AT ANY TIME.

§ 230.427 *Contents of prospectuses used after thirteen months.* Information contained in a registration statement may be omitted from a prospectus used more than 13 months after the effective date of the registration statement insofar as information on the same subjects but as of a date not more than 12 months prior to the use of the prospectus is contained therein. No amendment of the registration statement need be made in connection with the substitution of information pursuant to this section, but 20 copies of the prospectus proposed to be used shall be filed with the Commission pursuant to § 230.424 (c).

§ 230.428 *Invitations for competitive bids.* Any information or documents contained in a registration statement may be omitted from any newspaper advertisement which is only an invitation for competitive bids for the registered securities: *Provided*, (a) The terms of the bidding require that each bid shall be a firm bid for the purchase of the entire amount of such securities; and (b) the advertisement states that prior to the acceptance of any bid, the bidder will be furnished a copy of the official prospectus. In such case, no other requirements of the Commission with respect to newspaper prospectuses need be complied with. Such advertisement shall not be deemed a prospectus meeting the requirements of section 10 for the purpose of section 2 (10) (a) or 5 (b) (2) of the act.

§ 230.429 *Prospectus for employees' savings, profit sharing or pension plans.* (a) Any prospectus for shares of stock of an issuer in which funds of a savings, profit sharing or pension plan for employees of the issuer are to be invested need contain only the information specified below if the prospectus is sent or given only to employees of the issuer who have previously received a prospectus for registered interests or participations in the plan and for registered shares of stock of the issuer and who have become members of the plan prior to receipt of the prospectus prepared in accordance with this section:

(1) Such information (other than financial statements) in regard to the plan and the administration thereof and in regard to the issuer of the underlying stock and its subsidiaries as may be necessary to bring up to date the corresponding information furnished to members of the plan in previous prospectuses.

(2) Financial statements of the plan corresponding to those included in previous prospectuses for each fiscal year after the last fiscal year for which financial statements of the plan were furnished to members of the plan in previous prospectuses.

(3) Financial statements of the issuer of the underlying stock and its subsidiaries corresponding to those included in previous prospectuses for each fiscal year after the last fiscal year for which financial statements of the issuer and its subsidiaries were furnished to members of the plan in previous prospectuses.

(b) The financial statements specified in paragraph (a) of this section may be omitted from any prospectus used in the manner specified in that paragraph if:

(1) The fiscal year of the issuer of the underlying stock has ended within ninety days prior to the date when it is desired to distribute the prospectus to members of the plan.

(2) The prospectus contains, or is accompanied by, financial statements (which need not be certified) substantially meeting the requirements of paragraph (a) of this section.

(3) Within 120 days after the close of the fiscal year the financial statements omitted from the prospectus pursuant to this paragraph are made conveniently available to all members of the plan at their respective places of employment.

(4) There is set forth in conspicuous print on the first page of the prospectus a statement as to the manner in which and the approximate date on which the financial statements will be made available to members of the plan pursuant to subparagraph (3) of this paragraph.

WRITTEN CONSENTS

§ 230.435 *Consents of experts.* (a) All consents of experts filed with the registration statement pursuant to section 7 of the act shall be dated and shall be signed manually. All such consents, except those contained in the reports of experts, shall be attached after the signature page of the registration statement. Following the consents so attached, there shall be listed the names of all experts whose consents are contained in their reports and not attached after the signature page. After each name so listed a reference shall be made to the report containing the expert's consent.

(b) If any portion of the report of an expert is quoted or summarized in the registration statement or in a prospectus the written consent of the expert shall clearly identify the portion or portions of the report so quoted or summarized and shall expressly state that the expert consents to such quotation or summarization.

(c) If it is stated that any information contained in the registration statement has been reviewed or passed upon by any persons and that such information is set

forth in the registration statement upon the authority of or in reliance upon such persons as experts, the written consents of such persons shall be filed with the registration statement.

§ 230.436 *Application to dispense with consent.* An application to the Commission to dispense with any written consent of an expert pursuant to section 7 of the act shall be made by the registrant and shall be supported by an affidavit or affidavits establishing that the obtaining of such consent is impracticable or involves undue hardship on the registrant. Such application shall be filed and consent of the Commission shall be obtained prior to the effective date of the registration statement.

§ 230.437 *Consents of persons about to become directors.* If any person who has not signed the registration statement is named therein as about to become a director, the written consent of such person shall be filed with the registration statement. Any such consent, however, may be omitted if there is filed with the registration statement a statement by the registrant, supported by an affidavit or affidavits, setting forth the reasons for such omission and establishing that the obtaining of such consent is impracticable or involves undue hardship on the registrant. All consents filed pursuant to this section shall be dated, shall be signed manually, and shall be attached after the signature page of the registration statement and immediately following consents of experts and lists of consents, if any, filed pursuant to § 230.435.

§ 230.438 *Consent to use of material incorporated by reference.* If the act or the rules and regulations of the Commission require the filing of written consent to the use of any material in connection with the registration statement, such consent shall be filed with the registration statement even though the material is incorporated therein by reference.

EXHIBITS

§ 230.445 *Additional exhibits.* The registrant may file such exhibits as it may desire, in addition to those required by the appropriate form. Such exhibits shall be so marked as to indicate clearly the subject matters to which they refer.

§ 230.446 *Omission of substantially identical documents.* In any case where two or more indentures, contracts, franchises, patents, or other documents required to be filed as exhibits are substantially identical in all material respects except as to the parties thereto, the dates of execution, or other details, the registrant need file a copy of only one of such documents, with a schedule identifying the other documents omitted and setting forth the material details in which such documents differ from the document of which a copy is filed: *Provided, however,* That the Commission may at any time in its discretion require the filing of copies of any documents so omitted.

§ 230.447 *Incorporation of exhibits by reference.* (a) Any document or part thereof previously or concurrently filed with any office of the Commission pursuant to any act administered by the Commission may be incorporated by reference as an exhibit to any registration statement filed with any office of the Commission.

(b) If any modification has occurred in the text of any document incorporated by reference since the filing thereof, the registrant shall file with the reference a statement containing the text of any such modification and the date thereof.

(c) If the number of copies of any document previously or concurrently filed is less than the number required to be filed with the registration statement which incorporates such document as an exhibit, the registrant shall file with the registration statement as many additional copies of the document as may be necessary to meet the requirements of such statement.

§ 230.448 *Form of, and limitation upon, incorporation by reference.* (a) Material incorporated by reference shall be clearly identified in the reference. An express statement that the specified matter is incorporated by reference shall be made at the particular place in the statement where the information is required.

(b) Notwithstanding any particular provisions permitting incorporation by reference, the Commission may refuse to permit such incorporation in any case in which in its judgment such incorporation would render the statement incomplete, unclear or confusing.

FILING, FEES, EFFECTIVE DATE

§ 230.455 *Place of filing.* (a) Except as provided in paragraph (b) of this section, all registration statements shall be filed with the Commission at its principal office.

(b) If the principal executive offices of the registrant, or of a principal underwriter of the securities being registered, are located in the State of California, Nevada, Arizona, Oregon, Washington, Idaho, or Montana, or in the Territory of Hawaii, the registration statement may be filed with the regional office of the Commission in the Bank of America Building, 625 Market Street, San Francisco, Calif. However, the provisions of this paragraph shall not apply to registrants which are subject to the provisions of the Public Utility Holding Company Act of 1935 or the Investment Company Act of 1940.

§ 230.456 *Date of filing.* The date on which any papers are actually received in the proper office of the Commission pursuant to § 230.455 shall be the date of filing thereof, if all the requirements of the act and the rules with respect to such filing have been complied with and the required fee paid. The failure to pay an insignificant amount of the required fee at the time of filing, as the result of a bona fide error, shall not be deemed to affect the date of filing.

§ 230.457 *Computation of fee.* (a) At the time of filing a registration statement, the registrant shall pay to the Commission a fee of one one-hundredth of 1 percent of the maximum aggregate price at which the securities are proposed to be offered, but in no case shall such fee be less than $25.

(b) Where securities are to be offered at prices computed upon the basis of fluctuating market prices, the registration fee is to be calculated upon the basis of the price at which units of securities of the same class were or would have been sold on a specified date within fifteen days prior to the filing of the registration statement.

(c) Where securities are to be offered at varying prices based upon fluctuating values of underlying assets, the registration fee is to be calculated upon the basis of the market value of such assets as of a date within fifteen days prior to the date of filing, in accordance with the method to be used in calculating the daily offering price.

(d) Where securities are to be offered to existing security holders and the portion, if any, not taken by such security holders is to be reoffered to the general public, the registration fee is to be calculated upon the basis of the offering price to such security holders or the reoffering price to the general public, whichever is higher.

(e) Where securities are to be offered in exchange for other securities the registration fee is to be calculated upon whichever one of the following basis is applicable:

(1) The market value of the securities to be received by the registrant in exchange as established by bona fide transactions as of a date within fifteen days prior to the date of filing.

(2) If there be no market value thus established, the book value of the securities to be received by the registrant in exchange shall be used unless the issuer of the securities to be received in exchange is in bankruptcy or receivership, in which case one third of the principal amount, par value or stated value of the securities to be received in exchange shall be used.

However, where other securities of the same class as those to be offered in exchange are to be offered for cash, the maximum aggregate price shall be calculated upon the basis of the cash offering price or the basis specified above, whichever is higher. For the purposes of this paragraph, securities offered directly or indirectly in exchange for certificates of deposit shall be deemed to be offered in exchange for the securities represented by the certificates of deposit.

§ 230.458 *Payment of fee.* All payments of fees shall be made in cash, or by United States postal money order or certified check payable to the Securities and Exchange Commission, omitting the name or title of any official of the Commission.

§ 230.459 *Calculation of effective date.* The effective date of registration statements under section 8 (a) of the act shall be calculated as follows:

(a) Saturdays, Sundays and holidays shall be counted in computing the effective date.

(b) In the case of statements which become effective pursuant to section 8 (a) on the twentieth day after the filing thereof, the twentieth day shall be

deemed to begin at the expiration of nineteen periods, of twenty-four hours each, from 5:30 p. m. eastern time at the principal office on the date of filing.

§ 230.460 *Supplementary statement of actual offering price.* Within ten days after registered securities are initially offered to the public, the registrant shall file with the office of the Commission with which the registration statement was filed, a statement setting forth the actual price at which, and the date on which, the securities were so offered. If such price differs from the proposed price set forth in the registration statement, a brief explanation of such difference shall be made. Where the securities are to be offered first to existing security holders and then to the general public, a statement as required by this section shall be filed with respect to each of such offerings.

AMENDMENTS AND WITHDRAWALS

§ 230.470 *Formal requirements for amendments.* Amendments to the registration statement shall be filed under cover of the facing sheet of the appropriate form, and shall conform to all pertinent sections applicable to original registration statements. Amendments shall be numbered consecutively in the order in which filed with the Commission.

§ 230.471 *Signatures to amendments.* Except as provided in § 230.478, every amendment to a registration statement shall be signed by the persons specified in section 6 (a) of the act. At least the original of every amendment filed with the principal office of the Commission, and at least the original and one copy of every amendment filed with a regional office, shall be signed.

§ 230.472 *Filing of amendments; number of copies.* Except as provided in § 230.473, three copies of every amendment to the registration statement shall be filed. Where the amendment relates to the prospectus there shall be filed, in addition, five copies of the amended prospectus and five copies of the amended cross reference sheet required by § 230.404 (c). Amendments shall be filed with the office of the Commission with which the registration statement was filed.

§ 230.473 *Telegraphic delaying amendments.* An amendment altering the proposed date of the public offering may be made by telegram. Each such telegraphic amendment shall be confirmed within a reasonable time by the filing of three copies, one of which shall be signed. Such confirmation shall not be deemed an amendment.

§ 230.474 *Date of filing of amendments.* The date on which amendments are actually received in the office of the Commission with which the registration statement was filed shall be the date of filing thereof, if all of the requirements of the act and the rules with respect to such filing have been complied with.

§ 230.475 *Amendment filed with consent of Commission.* A registrant desiring the Commission's consent to the filing of an amendment with the effect provided in section 8 (a) of the act may apply for such consent at or before the time of filing the amendment. The application shall be signed and shall state fully the grounds upon which made. The Commission's consent shall be deemed to have been given and the amendment shall be treated as part of the registration statement upon the entry of an order to that effect.

§ 230.476 *Amendment filed pursuant to order of Commission.* An amendment made prior to the effective date of the registration statement shall be deemed to have been made pursuant to an order of the Commission within the meaning of section 8 (a) of the act so as to be treated as part of the registration statement only when the Commission shall after the filing of such amendment find that it has been filed pursuant to its order.

§ 230.477 *Withdrawal of registration statement or amendment.* Any registration statement or any amendment thereto may be withdrawn upon application if the Commission, finding such withdrawal consistent with the public interest and the protection of investors, consents thereto. The application for such consent shall be signed and shall state fully the grounds upon which made. The fee paid upon the filing of the registration statement will not be returned to the registrant. The papers comprising the registration statement or amendment thereto shall not be removed from the files of the Commission but shall be plainly marked with the date of the giving of such consent, and in the following manner: "Withdrawn upon the request of the registrant, the Commission consenting thereto."

§ 230.478 *Powers of agent for service to amend or withdraw registration statement.* Every registrant and all persons signing the registration statement, by naming an agent for service in the registration statement, shall be deemed, in the absence of a statement to the contrary, to confer upon such agent the following powers:

(a) A power to amend the registration statement by altering the date of the proposed offering of the securities for which the registration statement is filed.

(b) A power to amend the registration statement by filing any written consent of an expert required by section 7 of the act to be filed with the registration statement.

(c) A power to make application pursuant to § 230.475 for the Commission's consent to the filing of an amendment.

(d) A power to withdraw the registration statement or any amendment thereto.

(e) A power to consent to the entry of an order under section 8 (b) of the act, waiving notice and hearing, such order being entered without prejudice to the right of the registrant thereafter to have the order vacated upon a showing to the Commission that the registration statement as amended is no longer incomplete or inaccurate on its face in any material respect.

NONDISCLOSURE OF CONTRACT PROVISIONS

§ 230.485 *Contracts in general.* Public disclosure will not be made of the provisions of any material contract or portion thereof if the Commission determines that such disclosure would impair the value of the contract and is not necessary for the protection of investors. In any case where the registrant desires the Commission to make such a determination, the procedure set forth below shall be followed:

(a) The registrant shall omit from the registration statement as originally filed the portion of the contract which it desires to keep undisclosed, or, if the registrant desires to keep the entire contract undisclosed, any copy of the contract.

(b) The registrant shall file with the registration statement, but not bound as part thereof, (1) three copies of the contract or portion thereof which it desires to keep undisclosed, clearly marked "Confidential", and (2) an application for an order making the above described determination. Such application shall set forth the considerations relied upon for obtaining such order. Pending the granting or denial by the Commission of the application, the terms and existence of the contract or portion thereof will be kept undisclosed.

(c) If the Commission determines that the application shall be granted, an order to that effect will be entered. Prior to any determination denying the application, confirmed telegraphic notice of an opportunity for hearing, at a specified time within 10 days after the dispatch of such notice, will be sent to the agent for service. After such hearing, an order granting or denying the application will be entered.

(d) If the Commission denies the application, confirmed telegraphic notice of the order of denial will be sent to the agent for service. In such case, within 10 days after the dispatch of such notice, the registrant shall have the right to withdraw the registration statement in accordance with the terms of § 230.477, but without the necessity of stating any grounds for the withdrawal or of obtaining the further assent of the Commission. In the event of such withdrawal, the contract or portion thereof filed confidentially will be returned to the registrant.

(e) If the registration statement is not withdrawn pursuant to paragraph (d) of this section, the contract or portion thereof filed confidentially will be made available for public inspection as part of the registration statement, and the registrant shall amend the registration statement to include all information required to be set forth in regard to such contract or portion thereof.

§ 230.486 *Contracts affecting the national defense.* (a) Notwithstanding any requirement of the form used for registration, the registrant need not file as an exhibit to the registration statement a copy of any contract as to which all the following conditions are satisfied:

(1) A copy of the contract is on file with an executive department of the United States or with the United States Maritime Commission.

(2) The registrant has been notified in writing that the executive department or the United States Maritime Commission, as the case may be, has administratively determined that the subject of such contract relates to and affects the national defense and that disclosure thereof would be contrary to the public interest.

(b) The registrant shall file as an exhibit to the registration statement, in lieu of the copy of the contract omitted pursuant to paragraph (a) of this section, a copy of each notification received from the executive department or the United States Maritime Commission with respect to the filing of copies of the contract or of information as to its terms.

(c) Notwithstanding any requirement of the form used for registration, the registrant need not furnish any information as to any terms of the contract relating directly or indirectly to any of the following subjects as to which the registrant has been notified in writing that the executive department or the United States Maritime Commission with which a copy of the contract is on file has administratively determined that such subjects relate to and affect the national defense and that disclosure thereof would be contrary to the public interest:

(1) Quantity of equipment or materials to be constructed or supplied.

(2) Designations of type, descriptions, specifications, deliveries, test, or guarantees of performance with respect to such equipment or materials.

(3) Nature and extent of experimental facilities, services, or information to be furnished.

(d) Public disclosure will not be made of the contents of any notification filed pursuant to paragraph (b) of this section, or of any portion of the information as to the terms of the contract required to be furnished notwithstanding the provisions of paragraph (c) of this section, if the Securities and Exchange Commission determines that such disclosure would impair the value of the contract and is not necessary for the protection of investors. In any case where the registrant desires the Commission to make such a determination, the procedure set forth in § 230.485 shall be followed, except that there shall be filed in lieu of the three copies of the contract or portion thereof required by paragraph (b) (1) of § 230.485, three copies of the notification and three copies of the information as to the terms of the contract which the registrant desires to keep undisclosed, all clearly marked "Confidential".

REGISTRATION BY FOREIGN GOVERNMENTS OR POLITICAL SUBDIVISIONS THEREOF

§ 230.490 *Information to be furnished under paragraph (3) of Schedule B.* Any issuer filing a registration statement pursuant to Schedule B of the act need not furnish the detailed information specified in paragraph (3) as to issues of outstanding funded debt the aggregate amount of which outstanding is less than 5 percent of the total funded debt outstanding and to be created by the security to be offered: *Provided,* That the amount thereof is included in the statement of the total amount of funded debt outstanding: *And provided further,* That a statement is made as to the title, amount outstanding, rate of interest, and date of maturity of each such issue.

§ 230.491 *Information to be furnished under paragraph (6) of Schedule B.* Any foreign government filing a registration statement pursuant to Schedule B of the act need state, in furnishing the information required by paragraph (6), the names and addresses only of principal underwriters, namely, underwriters in privity of contract with the registrant: *Provided,* That they are designated as principal underwriters: *And provided further,* That a brief statement is made as to the discounts and commissions to be received by subunderwriters or dealers.

§ 230.492 *Omissions from prospectuses.* In the case of a security for which a registration statement conforming to Schedule B is in effect, the following information, contained in the registration statement, may be omitted from any prospectus: Information in answer to paragraph (3) of the schedule with respect to the amortization and retirement provisions for debt not being registered, and with respect to the provisions for the substitution of security for such debt; information in answer to paragraph (11); the copy of any agreement or agreements required by paragraph (13); the agreement required by paragraph (14); all information, whether contained in the registration statement itself or in any exhibit thereto, not required by Schedule B.

PROPOSED AMENDMENTS TO FORMS

Certain rules which specify the items of information required to be included in prospectuses are to be transferred from Regulation C to the respective forms to which they relate. The texts of the proposed amendments necessary to effect this transfer are as follows:

I. Form C–1 (see § 239.3, 11 F. R. 177A–731) is to be amended by inserting immediately after the "Rule as to the Use of Form C–1" the following:

Omissions from the Prospectus. The information required by the following items may be omitted from the prospectus: Items 4, 5, 7, 8, 9, 10, 18, 19, 33, 34, 37, 44, 45, 57, 58, 59, 61, 63, 70, 71 and 75.

The following exhibits may also be omitted from the prospectus: Exhibits A, B, C, E, F, G, H, I, J, K, L, M, N and R. Exhibit Q may be condensed.

II. Form D–1 (see § 239.6, 11 F. R. 177A–731) is to be amended by inserting immediately preceding "Part I" thereof the following:

Omissions from the Prospectus. The following information and documents may be omitted from the prospectus: In Part I, Items 4, 18, 39, and all exhibits except financial statements filed in compliance with Items 14 and 15; in Part II, Item 44 and all exhibits.

III. Form D–1A (see § 239.7, 11 F. R. 177A–732) is to be amended by inserting immediately after the General Instructions thereof the following:

Omissions from the Prospectus. The following information and documents may be omitted from the prospectus: All exhibits and all information contained in schedules, on condition that copies of each of the schedules attached to the registration statement are included.

IV. Form F–1 (see § 239.9, 11 F. R. 177A–732) is to be amended by adding at the end of the "Instructions as to preparing Form F–1" the following:

Omissions from the prospectus. The following information and documents may be omitted from the prospectus: Items 3, 26, 27 and all exhibits.

By the Commission.

[SEAL] ORVAL L. DUBOIS, *Secretary.*

MARCH 27, 1947.

[F. R. Doc. 47-3219; Filed, Apr. 3, 1947; 8:45 a. m.]

NOTICES

DEPARTMENT OF JUSTICE

Office of Alien Property

AUTHORITY: 40 Stat. 411, 55 Stat. 839, Pub. Laws 322, 671, 79th Cong., 60 Stat. 50, 925; 50 U. S. C. and Supp. App. 1, 616; E. O. 9193, July 6, 1942, 3 CFR, Cum. Supp., E. O. 9567, June 8, 1945, 3 CFR, 1945 Supp., E. O. 9788, Oct. 14, 1946, 11 F. R. 11981.

[Vesting Order 8488]

EISUKE ONO

In re: Bank account owned by and debt owing to Eisuke Ono, also known as E. Ono. F–39–331–A–1, F–39–331–E–1.

Under the authority of the Trading with the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Eisuke Ono, also known as E. Ono, whose last known address is Japan, is a resident of Japan and a national of a designated enemy country (Japan);

2. That the property described as follows:

a. That certain debt or other obligation owing to Eisuke Ono, also known as E. Ono, by The National City Bank of New York, 55 Wall Street, New York, New York, arising out of a Compound Interest Account, Account Number AN-13128, entitled E. Ono, maintained at the branch office of the aforesaid bank located at 257 Broadway, New York 7, New York, and any and all rights to demand, enforce and collect the same, and

b. That certain debt or other obligation owing to Eisuke Ono, also known as E. Ono, by Hunt, Hill & Betts, 120 Broadway, New York 5, N. Y., in the amount of $288.65, as of December 31, 1945, together with any and all accruals thereto, and any and all rights to demand, enforce and collect the same,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, the aforesaid national of a designated enemy country (Japan);

and it is hereby determined:

3. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Japan).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on March 20, 1947.

For the Attorney General.

[SEAL] DONALD C. COOK, *Director.*

[F. R. Doc. 47-3204; Filed, Apr. 2, 1947; 8:46 a. m.]

[Vesting Order 8489]

R. SASAKI

In re: Bank account owned by R. Sasaki also known as Ryoso Sasaki. F-39-2559-E-1.

Under the authority of the Trading with the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That R. Sasaki also known as Ryoso Sasaki, whose last known address is Japan, is a resident of Japan and a national of a designated enemy country (Japan);

2. That the property described as follows: That certain debt or other obligation owing to R. Sasaki also known as Ryoso Sasaki, by The National City Bank of New York, 55 Wall Street, New York, New York, arising out of a Checking Account, entitled R. Sasaki, and any and all rights to demand, enforce and collect the same,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, the aforesaid national of a designated enemy country (Japan);

and it is hereby determined:

3. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Japan);

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on March 20, 1947.

For the Attorney General.

[SEAL] DONALD C. COOK, *Director.*

[F. R. Doc. 47-3205; Filed, Apr. 2, 1947; 8:46 a. m.]

[Vesting Order 8490]

SANKO & CO.

In re: Debt owing to Sanko & Co. F-39-825-C-2.

Under the authority of the Trading with the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Sanko & Co., the last known address of which is Tokyo, Japan, is a corporation, partnership, association or other business organization, organized under the laws of Japan, and which has or, since the effective date of Executive Order 8389, as amended, has had its principal place of business in Japan and is a national of a designated enemy country (Japan);

2. That the property described as follows: That certain debt or other obligation owing to Sanko & Co., by Dodge & Seymour, Ltd., 53 Park Place, New York 7, New York, in the amount of $393.19, as of December 31, 1945, together with any and all accruals thereto, and any and all rights to demand, enforce and collect the same,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, the aforesaid national of a designated enemy country (Japan);

and it is hereby determined:

3. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Japan)..

All determinations and all action required by law, including appropriate consultation and certication, having been made and taken, and it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on March 20, 1947.

For the Attorney General.

[SEAL] DONALD C. COOK, *Director.*

[F. R. Doc. 47-3206; Filed, Apr. 2, 1947; 8:46 a. m.]

[Vesting Order 8491]

HEDWICH SCHURMANN

In re: Bank account owned by Hedwich Schurmann also known as Hedwig Schurmann and Hedwig Schuermann. F-28-12197-E-1.

Under the authority of the Trading with the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Hedwich Schurmann, also known as Hedwig Schurmann and Hedwig Schuermann, whose last known address is Germany, is a resident of Germany and a national of a designated enemy country (Germany);

2. That the property described as follows: That certain debt or other obligation of The Northern Trust Company, 50 South LaSalle Street, Chicago, Illinois, arising out of a checking account, entitled Cloidt, George W., Trustee Under Trust Agreement Dated Oct. 3, 1935, Known as Wachsman, and any and all rights to demand, enforce and collect the same,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, Hedwich Schurmann, also known as Hedwig Schurmann and Hedwig Schuermann, the aforesaid national of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on March 20, 1947.

For the Attorney General.

[SEAL] DONALD C. COOK, *Director.*

[F. R. Doc. 47-3207; Filed, Apr. 2, 1947; 8:46 a. m.]

[Vesting Order 8497]

KOSAKU WATANABE

In re: Bank account owned by Kosaku Watanabe.

Under the authority of the Trading with the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Kosaku Watanabe, whose last known address is Japan, is a resident of Japan and a national of a designated enemy country (Japan);

2. That the property described as follows: That certain debt or other obligation owing to Kosaku Watanabe, by The Chase National Bank of the City of New York, 18 Pine Street, New York, New York, arising out of an inactive dollar checking account, entitled K. (Kosaku) Watanabe, and any and all rights to demand, enforce and collect the same,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, the aforesaid national of a designated enemy country (Japan);

and it is hereby determined:

3. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Japan).

All determinations and all action required by law, including appropriate consultation and certication, having been made and taken, and it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on March 20, 1947.

For the Attorney General.

[SEAL] DONALD C. COOK, *Director.*

[F. R. Doc. 47-3208; Filed, Apr. 2, 1947; 8:46 a. m.]

[Vesting Order 7445, Amdt.]

DR. RICHARD NUNNINGHOFF

In re: Debt owing to and stocks and bonds owned by Dr. Richard Nunninghoff.

Vesting Order 7445, dated August 15, 1946, is hereby amended as follows and not otherwise:

By deleting clause (c) from subparagraph 2 of said Vesting Order 7445 and substituting therefor the following:

c. Those certain bonds described in Exhibit A, attached hereto and by reference made a part hereof, presently in the custody of Hallgarten & Co., 44 Wall Street, New York 5, New York, together with any and all rights thereunder and thereto,

All other provisions of said Vesting Order 7445 and all actions taken by or on behalf of the Alien Property Custodian or the Attorney General of the United States in reliance thereon, pursuant thereto and under the authority thereof are hereby ratified.

Executed at Washington, D. C., on March 27, 1947.

For the Attorney General.

[SEAL] DONALD C. COOK, *Director.*

[F. R. Doc. 47-3209; Filed, Apr. 2, 1947; 8:46 a. m.]

[Vesting Order 8402]

KEI YASHUHARA AND JAMES KUROMI

In re: Debts owing to Kei Yasuhara, also known as K. Yasuhara, and James Kuromi, also known as James Isao Kuromi. D-39-664-E-1, F-39-5557-E-1.

Under the authority of the Trading with the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and purusant to law, after investigation, it is hereby found:

1. That Kei Yasuhara, also known as K. Yasuhara, and James Kuromi, also known as James Isao Kuromi, each of whose last known address is Japan, are residents of Japan and nationals of a designated enemy country (Japan);

2. That the property described as follows:

a. That certain debt or other obligation owing to Kei Yasuhara, also known as K. Yasuhara, by the Superintendent of Banks of the State of California and Liquidator of The Yokohama Specie Bank, Ltd., Los Angeles Office, c/o State Banking Department, 111 Sutter Street, San Francisco, California, in the amount of $1,387.19, as of December 31, 1945, arising out of a commercial checking account entitled K. Yasuhara (Kei Yasuhara), together with any and all accruals thereto, and any and all rights to demand, enforce and collect the same, and

b. That certain debt or other obligation owing to James Kuromi, also known as James Isao Kuromi, by the Superintendent of Banks of the State of California and Liquidator of The Yokohama Specie Bank, Ltd., Los Angeles Office, c/o State Banking Department, 111 Sutter Street, San Francisco, California, in the amount of $1,011.28, as of December 31, 1945, arising out of Fixed Deposit Certificate Number 69509, together with any and all accruals thereto, and any and all rights to demand, enforce and collect the same,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, the aforesaid nationals of a designated enemy country (Japan);

and it is hereby determined:

3. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Japan).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on March 6, 1947.

For the Attorney General.

[SEAL] DONALD C. COOK, *Director.*

[F. R. Doc. 47-3243; Filed, Apr. 3, 1947; 8:46 a. m.]

[Vesting Order CE 374]

COSTS AND EXPENSES INCURRED IN CERTAIN ACTIONS OR PROCEEDINGS IN CERTAIN CALIFORNIA COURTS

Under the authority of the Trading with the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it having been found:

1. That each of the persons named in Column 1 of Exhibit A, attached hereto and by reference made a part hereof, was a person within the designated enemy country or the enemy-occupied territory identified in Column 2 of said Exhibit A opposite such person's name;

2. That it was in the interest of the United States to take measures in connection with representing each of said persons in the court or administrative action or proceeding identified in Column 3 of said Exhibit A opposite such person's name, and such measures having been taken;

3. That, in taking such measures in each of such actions or proceedings, costs and expenses have been incurred in the amount stated in Column 4 of said Exhibit A opposite the action or proceeding identified in Column 3 of said Exhibit A;

Now, therefore, there is hereby vested in the Attorney General of the United States, to be used or otherwise dealt with in the interest of and for the benefit of the United States, interests in the property which said persons obtain or are determined to have as a result of said actions or proceedings in amounts equal to the sums stated in Column 4 of said Exhibit A.

The term "designated enemy country" as used herein shall have the meaning prescribed in section 10 of Executive Order 9193, as amended. The term "enemy-occupied territory" as used herein shall have the meaning prescribed in Rules of Procedure, Office of Alien Property, § 501.6 (8 CFR, Cum. Supp., 503.6).

Executed at Washington, D. C., on March 31, 1947.

For the Attorney General.

[SEAL] DONALD C. COOK,
Director.

EXHIBIT A

Column 1 Name	Column 2 Country or territory	Column 3 Action or proceeding	Column 4 Sum vested
		Item 1	
Sarah Oliverio	Italy	Estate of Paul Oliverio, deceased, in the Superior Court of the State of California, in and for the county of Los Angeles; No. 256991.	$11.00
		Item 2	
Asunta Oliverio	do	Same	11.00
		Item 3	
Maria Rosa Oliverio	do	Same	11.00
		Item 4	
Maria Oliverio	do	Same	11.00
		Item 5	
Agostino Vallarino	do	Estate of Ambrogio Vallarino, deceased, in the Superior Court of the State of California, in and for the city and county of San Francisco; No. 60408.	13.00
		Item 6	
Giovanni Vallarino	do	Same	13.00
		Item 7	
Gerolamo Vallarino	do	Same	13.00
		Item 8	
Giuseppina Vallarino	do	Same	13.00
		Item 9	
Mariam Pellegrinelli	do	Estate of Chris Pellegrinelli, deceased, in the Superior Court of the State of California, in and for the county of Siskiyou; No. 4227.	13.00
		Item 10	
Luigi Pellegrinelli	do	Same	13.00
		Item 11	
Guisippe Pellegrinelli	do	Same	13.00
		Item 12	
Brother, name unknown, of Carlo Paganucci, deceased.	do	Estate of Carlo Paganucci, deceased, in the Superior Court of the State of California, in and for the city and county of San Francisco; No. 89794.	26.00
		Item 13	
Alberto Veglio	do	Estate of Cesar Veglio, deceased, in the Superior Court of the State of California, in and for the city and county of San Francisco; No. 93311.	15.00
		Item 14	
Ernesta Veglio	do	Same	15.00
		Item 15	
Emma Veglio	do	Same	15.00
		Item 16	
Louis Tognonalli	do	Estate of Peter Tognonalli, also known as Pietro Tognonalli, also known as Pete Tognonalli, also known as Pietro Tognonalli, also known as Pietro Francesco Tognonalli, also known as P. Tognonali, also known as Pietro Tognonalli, deceased, in the Superior Court of the State of California, in and for the county of San Mateo, No. 10033.	13.00
		Item 17	
Maria Tognonalli	do	Same	13.00
		Item 18	
Assunta Rosai or her issue	do	Estate of Ermenegildo Massa, deceased, in the Superior Court of the State of California, in and for the county of Sonoma; No. 11849.	15.00
		Item 19	
Ottavia Martini or her issue	do	Same	15.00
		Item 20	
Joseph Abate	do	Estate of Vincent Abate, deceased, in the Superior Court of the State of California, in and for the city and county of San Francisco; No. 93106.	34.00
		Item 21	
Frederick Abate	do	Same	34.00

EXHIBIT A—Continued

Column 1 Name	Column 2 Country or territory	Column 3 Action or proceeding	Column 4 Sum vested
		Item 22	
Maria Basile	Italy	Estate of Giuseppe Filippelli, deceased, in the Superior Court of the State of California, in and for the county of Los Angeles; No. 225710.	$23.00
		Item 23	
Nicola Filippelli	do	Same	23.00
		Item 24	
Children, names unknown, of Caterina Angelosanti.	do	Estate of Biagio Angelosanti, also known as B. Angelo, deceased, in the Superior Court of the State of California, in and for the county of Los Angeles; No. 234737.	80.00
		Item 25	
Children, names unknown, of Natalina Angelosanti.	do	Same	80.00
		Item 26	
Amalio Paone	do	Estate of Pietro Paone, deceased, in the Superior Court of the State of California, in and for the city and county of San Francisco; No. 100785.	68 00
		Item 27	
Gioletta Gestra Matteri	do	Estate of Luigi Gestra, also known as Louy Gestra, also known as Loucy Gestra, also known as Louie Gestra, also known as Louis Gestra, also known as Louca Gestra, deceased, in the Superior Court of the State of California, in and for the county of Sonoma; No. 1559Z.	60.00
		Item 28	
Joseph Bellino	do	Estate of Donato Bellino, deceased, in the Superior Court of the State of California, in and for the city and county of San Francisco; No. 93800.	31.00
		Item 29	
Heirs, next of kin and legatees of Filomena Guasti Grossetti.	do	Estate of Louisa Guasti, also known as Louisa A. Guasti, deceased, in the Superior Court of the State of California, in and for the county of Los Angeles; No. 167982.	67.00

[F. R. Doc. 47-3250; Filed, Apr. 3, 1947; 8:47 a. m.]

[Vesting Order 8538]

FUSAJIRO ISHII

In re: Stock owned by Fusajiro Ishii, F-39-5699-D-1.

Under the authority of the Trading with the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Fusajiro Ishii, whose last known address is Tokyo, Japan, is a resident of Japan and a national of a designated enemy country (Japan);

2. That the property described as follows: Thirty (30) shares of $20.00 par value capital stock of The S. S. White Dental Manufacturing Co., a corporation organized under the laws of the State of Pennsylvania, evidenced by certificates numbered 1463 for twenty-five (25) shares and 1804 for five (5) shares registered in the name of Fusajiro Ishii, together with all declared and unpaid dividends thereon,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, the aforesaid national of a designated enemy country (Japan);

and it is hereby determined:

3. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Japan).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on March 25, 1947.

For the Attorney General.

[SEAL] DONALD C. COOK, *Director.*

[F. R. Doc. 47-3245; Filed, Apr. 4, 1947; 8:46 a. m.]

[Vesting Order CE 373]

COSTS AND EXPENSES INCURRED IN CERTAIN ACTIONS OR PROCEEDINGS IN CERTAIN CALIFORNIA COURTS

Under the authority of the Trading with the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it having been found:

1. That each of the persons named in Column 1 of Exhibit A, attached hereto and by reference made a part hereof, was a person within the designated enemy country or the enemy-occupied territory identified in Column 2 of said Exhibit A opposite such person's name;

2. That it was in the interest of the United States to take measures in connection with representing each of said persons in the court or administrative action or proceeding identified in Column 3 of said Exhibit A opposite such person's name, and such measures having been taken;

3. That, in taking such measures in each of such actions or proceedings, costs and expenses have been incurred in the amount stated in Column 4 of said Exhibit A opposite the action of proceeding identified in Column 3 of said Exhibit A;

Now, therefore, there is hereby vested in the Attorney General of the United States, to be used or otherwise dealt with in the interest of and for the benefit of the United States, interests in the property which said persons obtain or are determined to have as a result of said actions or proceedings in amounts equal to the sums stated in Column 4 of said Exhibit A.

The term "designated enemy country" as used herein shall have the meaning prescribed in section 10 of Executive Order 9193, as amended. The term "enemy-occupied territory" as used herein shall have the meaning prescribed in Rules of Procedure, Office of Alien Property, § 501.6 (8 CFR, Cum. Supp., 503.6).

Executed at Washington, D. C., on March 31, 1947.

For the Attorney General.

[SEAL] DONALD C. COOK, *Director.*

EXHIBIT A

Column 1 Name	Column 2 Country or territory	Column 3 Action or proceeding	Column 4 Sum vested
		Item 1	
Caterina Capurro	Italy	Estate of Giuseppe Capurro, deceased, in the Superior Court of the State of California, in and for the county of San Joaquin; No. 16279.	$9.00
		Item 2	
Giobata Capurro	do	Same	9.00
		Item 3	
Angelo Capurro	do	Same	9.00
		Item 4	
Antonio Capurro	do	Same	9.00
		Item 5	
Louisa Capurro	do	Same	9.00
		Item 6	
Surviving issue, names unknown, of Julia Pissotti	do	Same	9.00
		Item 7	
Giovanni Accinelli	do	Estate of Gino Accinelli, also known as Gerolamo Accinelli, deceased, in the Superior Court of the State of California, in and for the county of Alameda; No. 09103.	14.00
		Item 8	
Giuseppe Accinelli	do	Same	14.00
		Item 9	
Paolo Accinelli	do	Same	14.00
		Item 10	
Angela Accinelli	do	Same	14.00
		Item 11	
Catterina Accinelli	do	Same	14.00
		Item 12	
Benedetta C. Ruggieri	do	Estate of Michele Colacurdo, deceased, in the Superior Court of the State of California, in and for the county of Los Angeles; No. 208672.	13.00
		Item 13	
Maria C. Cauzzilli	do	Same	13.00
		Item 14	
Maria Luigi Tedesco	do	Estate of Giovanni Tedesco, deceased, in the Superior Court of the State of California, in and for the city and county of San Francisco; No. 102990.	10.00
		Item 15	
Maria Arcangela Tedesco	do	Same	10.00
		Item 16	
Angela Tedesco	do	Same	10.00
		Item 17	
Rosaria Dimitri	do	Same	10.00
		Item 18	
Children of deceased sister, Immacalta Tedesco	do	Same	10.00
		Item 19	
Vittorio Porliod	do	Estate of Alex Porliod, also known as Alexis Porliod, also known as A. Porliod, deceased, in the Superior Court of the State of California; in and for the county of Fresno; No. 17062.	13.00
		Item 20	
Augusto Porliod	do	Same	13.00
		Item 21	
Emanuele Porliod	do	Same	13.00
		Item 22	
Rosalia Champienz and her children, names unknown.	do	Same	20.00
		Item 23	
Rosetta Pedretti	do	Estate of Ferruccio Pedretti, deceased, in the Superior Court of the State of California, in and for the county of Alameda; No. 83152.	15.00
		Item 24	
Gina Martinucci	do	Same	8.00
		Item 25	
Aldo Martinucci	do	Same	5.00
		Item 26	
Silvio Martinucci	do	Same	5.00
		Item 27	
Giovanni Valenzano	do	Estate of Secondo Valenzano, deceased, in the Superior Court of the State of California, in and for the county of San Mateo; No. 12262.	39.00
		Item 28	
Francisco Valenzano	do	Same	39.00
		Item 29	
Maria Valenzano	do	Same	39.00
		Item 30	
Antonio Valenzano	do	Same	39.00

EXHIBIT A—Continued

Column 1 Name	Column 2 Country or territory	Column 3 Action or proceeding	Column 4 Sum vested
		Item 31	
Giuseppe Bonelli	Italy	Estate of Pietro Bonelli, deceased, in the Superior Court of the State of California, in and for the city and county of San Francisco; No. 90695.	$8.00
		Item 32	
Giovanni Bonelli	do	Same	8.00
		Item 33	
Luigi Bonelli	do	Same	8.00
		Item 34	
Amalia Farotto	do	Same	8.00
		Item 35	
Francesco Torre	do	Estate of John Torre, deceased, in the Superior Court of the State of California, in and for the county of Alameda; No. 67948.	12.00
		Item 36	
Pietro Torre	do	Same	12.00
		Item 37	
Madelena Torre	do	Same	12.00
		Item 38	
Fernanda Ricci	do	Estate of Luigi Ricci, also known as Louie Ricci, deceased, in the Superior Court of the State of California, in and for the county of Sonoma; No. 17093.	20.00
		Item 39	
Fernando Ricci	do	Same	10.00
		Item 40	
Francisco Ricci	do	Same	10.00
		Item 41	
Mrs. Margherita Agnolesi	do	Estate of Henry L. Choistry, deceased, in the Superior Court of the State of California, in and for the county of Los Angeles; No. 227,377.	78.00
		Item 42	
Maria F. L. Raffeto	do	Estate of Carlo Emanuele Raffetto, also known as Carlo Raffetto, also known as C. Raffetto, also known as Charles Raffetto, deceased, in the Superior Court of the State of California, in and for the city and county of San Francisco; No. 76869.	153.00
		Item 43	
Rosa Carbone also known as Zita Carbone or Issue of Rosa Carbone, also known as Zita Carbone or Oreste Carbone and Angelo Carbone.	do	Estate of Emanuele F. Simonini, deceased, in the Superior Court of the State of California, in and for the county of Solano; No. 8266.	53.00
		Item 44	
Argentina Innocenti	do	Estate of Quintilio Innocenti, deceased, in the Superior Court of the State of California, in and for the city and county of San Francisco; No. 93161.	84.00

[F. R. Doc. 47-3249; Filed, Apr. 3, 1947; 8:47 a. m.]

[Vesting Order 8543]

FREDERICH WILHELM RILL

In re: Stock owned by Frederich Wilhelm Rill. F-28-5851-D-1/2.

Under the authority of the Trading with the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Frederich Wilhelm Rill, whose last known address is Schneebergstrasse 1, Lindau, Bodensee, Germany, is a resident of Germany and a national of a designated enemy country (Germany);

2. That the property described as follows:

a. Fifty (50) shares of no par value common capital stock of General Electric Company, 1 River Road, Schnectady, New York, a corporation organized under the laws of the State of New York, evidenced by certificate number NYD-516514, registered in the name of Frederich Wilhelm Rill, together with all declared and unpaid dividends thereon, and

b. Eight (8) shares of no par value common capital stock of Radio Corporation of America, 30 Rockefeller Plaza, New York, New York, a corporation organized under the laws of the State of Delaware, evidenced by certificate number FWO2411, registered in the name of Frederich Wilhelm Rill, together with all declared and unpaid dividends thereon,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, the aforesaid national of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt within the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on March 25, 1947.

For the Attorney General.

[SEAL] DONALD C. COOK, *Director.*

[F. R. Doc. 47-3246; Filed, Apr. 3, 1947; 8:46 a. m.]

[Vesting Order CE 375]

COSTS AND EXPENSES INCURRED IN CERTAIN ACTIONS OR PROCEEDINGS IN CERTAIN CALIFORNIA COURTS

Under the authority of the Trading with the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it having been found:

1. That each of the persons named in Column 1 of Exhibit A, attached hereto

and by reference made a part hereof, was a person within the designated enemy country or the enemy-occupied territory identified in Column 2 of said Exhibit A opposite such person's name;

2. That it was in the interest of the United States to take measures in connection with representing each of said persons in the court or administrative action or proceeding identified in Column 3 of said Exhibit A opposite such person's name, and such measures having been taken;

3. That, in taking such measures in each of such actions or proceedings, costs and expenses have been incurred in the amount stated in Column 4 of said Exhibit A opposite the action or proceeding identified in Column 3 of said Exhibit A;

Now, therefore, there is hereby vested in the Attorney General of the United States, to be used or otherwise dealt with in the interest of and for the benefit of the United States, interests in the property which said persons obtain or are determined to have as a result of said actions or proceedings in amounts equal to the sums stated in Column 4 of said Exhibit A.

The term "designated enemy country" as used herein shall have the meaning prescribed in section 10 of Executive Order 9193, as amended. The term "enemy-occupied territory" as used herein shall have the meaning prescribed in Rules of Procedure, Office of Alien Property, § 501.6 (8 CFR, Cum. Supp., 503.6).

Executed at Washington, D. C., on March 31, 1947.

For the Attorney General.

[SEAL] DONALD C. COOK, *Director.*

EXHIBIT A

Column 1 Name	Column 2 Country or territory	Column 3 Action or proceeding	Column 4 Sum vested
		Item 1	
Maria Robustellini	Italy	Estate of Antonio Louis Robustellini, also known as Antonio Luigi Robustellini, also known as Luigi Robustellini, also known as Louis Robustellini, also known as Louis A. Robustellini, also known as Louis Antonio Robustellini, also known as Louis Robustelli, also known as Luigi Robustelli, deceased, Superior Court, Nevada County, Calif.; No. 4278.	$35.00
		Item 2	
Domenica Robustellini	do	Same	35.00
		Item 3	
Cesarina Melchiori	do	Estate of Adriano Melchiori, also known as A. Melchiori, also known as Adrian Melchiori, also known as Adrian Melchior, deceased, Superior Court, Nevada County, Calif.; No. 4410.	25.00
		Item 4	
Silvia Melchiori	do	Same	25.00
		Item 5	
Antonina Gioia	do	Estate of Pietro Gioia, deceased, Superior Court, Los Angeles County, Calif.; No. 259729.	04.00
		Item 6	
Renzo Bonini	do	Estate of Olinto Bonini, deceased, Superior Court, city and county of San Francisco, Calif.; No. 67278.	25.00
		Item 7	
Renzo Bonini	do	Estate of Albert Bonini, deceased, Superior Court, city and county of San Francisco, Calif.; No. 13444.	25.00

[F. R. Doc. 47-3252; Filed, Apr. 3, 1947; 8:47 a. m.]

[Vesting Order 8546]

FRIDA NAKASA ET AL.

In re: Watch owned by Frieda Nakasa, also known as Frida Lucie Nakasa, and the personal representatives, heirs, next of kin, legatees and distributees of Miyanosuka Nakasa, also known as M. Nakasa, deceased.

Under the authority of the Trading with the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Frieda Nakasa, also known as Frida Lucie Nakasa, whose last known address is 25 Alter Steinweg, Hamburg, Germany, is a resident of Germany and a national of a designated enemy country (Germany);

2. That the personal representatives, heirs, next of kin, legatees and distributees of Miyanosuke Nakasa, also known as M. Nakasa, deceased, who there is reasonable cause to believe are residents of Germany, are nationals of a designated enemy country (Germany);

3. That the property described as follows: One yellow metal "Lanco" man's watch, whose case bears the number 18245, presently in the possession of the Attorney General of the United States,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, the aforesaid nationals of a designated enemy country (Germany);

and it is hereby determined:

4. That to the extent that Frieda Nakasa, also known as Frida Lucie Nakasa, and the personal representatives, heirs, next of kin, legatees and distributees of Miyanosuke Nakasa, also known as M. Nakasa, deceased, are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on March 27, 1947.

For the Attorney General.

[SEAL] DONALD C. COOK, *Director.*

[F. R. Doc. 47-3248; Filed, Apr. 3, 1947; 8:46 a. m.]

[Vesting Order 8496]

JOHN WALCH

In re: Stock owned by John Walch. F-28-22287-D-1, F-28-22287-D-2.

Under the authority of the Trading with the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That John Walch, whose last known address is Germany, is a resident of Germany and a national of a designated enemy country (Germany);

2. That the property described as follows:

a. Five (5) shares of $100.00 par value 6½% cumulative preferred capital stock of Empire Gas and Fuel Company, 60 Wall Street, New York 5, New York, a corporation organized under the laws of the State of Delaware, evidenced by a certificate numbered 2920, and registered in the name of John Walch, together with all declared and unpaid dividends thereon, and all rights thereunder and thereto, including particularly the right of redemption,

b. Twenty-one (21) shares of $10.00 par value common capital stock of Cities Service Company, 60 Wall Street, New York 5, New York, a corporation organized under the laws of the State of Delaware, evidenced by a certificate numbered 57906, and registered in the name of John Walch, together with all declared and unpaid dividends thereon,

c. Seven (7) shares of no par value $6.00 cumulative preferred capital stock of Cities Service Company, 60 Wall Street, New York 5, New York, a corporation organized under the laws of the State of Delaware, evidenced by a certificate numbered 85725, and registered in the name of John Walch, together with all declared and unpaid dividends thereon, and

d. Four (4) shares of no par value $6.00 cumulative preference BB capital stock of Cities Service Company, 60 Wall Street, New York 5, New York, a corporation organized under the laws of the State of Delaware, evidenced by a certificate numbered 795, and registered in the name of John Walch, together with all declared and unpaid dividends thereon,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, the aforesaid national of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on March 20, 1947.

For the Attorney General.

[SEAL] DONALD C. COOK,
Director.

[F. R. Doc. 47-3244; Filed, Apr. 3, 1947; 8:46 a. m.]

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

ALASKA

AIR-NAVIGATION SITE WITHDRAWAL NO. 139 REDUCED

The order of the Assistant Secretary of the Interior dated March 29, 1940, withdrawing certain tracts of public land in Alaska for the use of the Alaska Road Commission in the maintenance of air-navigation facilities, is hereby revoked so far as it affects the following lands described by metes and bounds:

Beginning at Corner No. 1, which is identical with Corner No. 4 of U. S. Survey No. 397 at Tanana, in approximate latitude 65° 10' N., longitude 152°04' W.; thence from said Corner No. 1, by metes and bounds, S. 39°37' E. 1,300 feet to Corner No. 2; N. 82°18' E. 4,491.6 feet to Corner No. 3; North 4,679 feet to Corner No. 4; West 5,280 feet to Corner No. 5 on line 4–5 of U. S. Survey No. 397; South 4,279.4 feet along line 4–5 of Survey No. 397 to Corner No. 1, the place of beginning.

The tract as described contains 599.8 acres.

This order shall not otherwise become effective to change the status of such lands until 10:00 a. m. on May 23, 1947.

At that time the lands shall become subject to settlement and other forms of appropriation in accordance with the applicable public land laws and regulations.

This land lies adjacent to and north of the Yukon River at Tanana Village and is about four (4) miles to the west of the junction of the Yukon and Tanana Rivers. The land is in general level and supports only a sparse cover of vegetation.

[SEAL] C. GIRARD DAVIDSON,
Assistant Secretary of the Interior.

MARCH 21, 1947.

[F. R. Doc. 47-3214; Filed, Apr. 3, 1947; 8:46 a. m.]

OREGON

TIMBER PRESERVATION AREA ESTABLISHED

By virtue of the authority contained in the act of August 28, 1937, 50 Stat. 874, it is ordered as follows:

Subject to valid existing rights and existing withdrawals, the following-described revested Oregon and California Railroad grant lands are hereby classified as timber lands and reserved for administration by the Bureau of Land Management, as a timber preservation area, and for the protection of their recreational and scenic values:

WILLAMETTE MERIDIAN

T. 1 S., R. 5 E.,
Sec. 1, lots 3 and 4;
Sec. 3, lot 1.

The areas described aggregate 113.05 acres.

Trees may be cut only under the supervision of the Regional Administrator, Bureau of Land Management, as and when deemed necessary in order that the reserved area may be maintained properly.

[SEAL] C. GIRARD DAVIDSON,
Assistant Secretary of the Interior.

MARCH 18, 1947.

[F. R. Doc. 47-3215; Filed, Apr. 3, 1947; 8:46 a. m.]

OREGON

NOTICE FOR FILING OBJECTIONS TO THE ORDER ESTABLISHING A TIMBER PRESERVATION AREA

Notice is hereby given that for a period of 30 days from the date of publication of this notice, persons having cause to object to the terms of the order of March 18, 1947, withdrawing lots 3 and 4, sec. 1, and lot 1, sec. 3, T. 1 S., R. 5 E., W. M., Oregon, which are revested Oregon and California Railroad grant lands, for administration by the Bureau of Land Management, as a timber preservation area, may present their objections to the Secretary of the Interior. Such objections should be in writing, should be addressed to the Secretary of the Interior, and should be filed in duplicate in the Department of the Interior, Washington 25, D. C.

In case any objection is filed and the nature of the opposition is such as to warrant it, a public hearing will be held at a convenient time and place, which will be announced, where opponents to the order may state their views and where the proponents of the order can explain its purpose, intent and extent. Whether or not a hearing is held, notice of the determination by the Secretary as to whether the order should be rescinded, modified or let stand will be given to all interested parties of record and the general public.

[SEAL] C. GIRARD DAVIDSON,
Assistant Secretary of the Interior.

MARCH 18, 1947.

[F. R. Doc. 47-3216; Filed, Apr. 3, 1947; 8:46 a. m.]

DEPARTMENT OF AGRICULTURE

Production and Marketing Administration

[P. & S. Docket No. 1510]

ESSEX COUNTY COOP CO.

NOTICE OF PETITION FOR EXTENSION OF TEMPORARY RATES

Pursuant to the provisions of the Packers and Stockyards Act, 1921, as amended (7 U. S. C. 181 et seq.), the Secretary of Agriculture on April 5, 1946, issued an order requiring the respondent to increase its rates for the rental of chicken coops from 48 cents to 68 cents and for turkey coops from 65 cents to 85 cents for a period of one year from the date of that order.

By petition filed on March 26, 1947, the respondent has requested that the

rates and charges provided for in said order of April 5, 1946, be extended for a further period of at least one year.

It appears that public notice should be given of the filing of such petition in order that all interested persons may have an opportunity to be heard in the matter.

Now, therefore, notice is hereby given to the public and to all interested persons of the filing of such petition for extension of temporary rates.

All interested persons who desire to be heard upon the matter requested in said petition shall notify the Hearing Clerk, United States Department of Agriculture, Washington 25, D. C., within 15 days from the date of the publication of this notice.

Copies hereof shall be served upon the respondent by registered mail or in person.

Done at Washington, D. C., this 31st day of March 1947.

[SEAL] H. E. REED,
Director, Livestock Branch.

[F. R. Doc. 47-3240; Filed, Apr. 3, 1947; 8:45 a. m.]

FEDERAL COMMUNICATIONS COMMISSION

[Designation Order 8]

DESIGNATION OF MOTIONS COMMISSIONER FOR APRIL 1947

At a session of the Federal Communications Commission held at its offices in Washington, D. C. on the 27th day of March 1947;

It is ordered, Pursuant to § 1.111 of the Commission's rules and regulations, that E. K. Jett, Commissioner, be, and he is hereby designated as Motions Commissioner, for the month of April 1947.

It is further ordered, That in the event said Motions Commissioner is unable to act during any part of said period the Chairman or Acting Chairman will designate a substitute Motions Commissioner.

[SEAL] FEDERAL COMMUNICATIONS COMMISSION,
T. J. SLOWIE,
Secretary.

[F. R. Doc. 47-3253; Filed, Apr. 3, 1947; 8:46 a. m.]

[Docket Nos. 8176, 8177, 8265]

TERRELL BROADCAST CORP. ET AL.

ORDER DESIGNATING APPLICATION FOR CONSOLIDATED HEARING ON STATED ISSUES

In re applications of Terrell Broadcast Corporation, Terrell, Texas, Docket No. 8176, File No. BP-5778; Burton V. Hammond, Jr., Denison, Texas, Docket No. 8177, File No. BP-5786; Conn & Cope, d/b as Denison-Texoma Broadcasting Company, a partnership composed of Fred Conn and Millard Cope Denison, Texas, Docket No. 8265, File No. BP-5403; for construction permits.

At a session of the Federal Communications Commission, held at its offices in Washington, D. C., on the 27th day of March 1947;

The Commission having under consideration the above-entitled application of Conn & Cope, doing business as Denison-Texoma Broadcasting Company, a partnership composed of Fred Conn and Millard Cope, requesting a permit to construct a new standard broadcast station to operate on 1250 kc, 1 kw power, daytime only at Denison, Texas; and also having under consideration a petition filed on March 14, 1947, by Burton V. Hammond, Jr., requesting that said application be designated for hearing in the consolidated proceeding involving the other two applications named above;

It appearing, that the Commission on March 6, 1947, designated for hearing in a consolidated proceeding the applications of Terrell Broadcast Corporation (File No. BP-5778; Docket No. 8176) requesting a construction permit for a new standard broadcast station to operate on 1220 kc, 250 w power, daytime only at Terrell, Texas, and Burton V. Hammond, Jr., (File No. BP-5786; Docket No. 8177) requesting a construction permit for a new standard broadcast station to operate on 1220 kc, 1 kw power, daytime only at Denison, Texas.

It is ordered, That the said petition of Burton V. Hammond, Jr., be, and it is hereby, granted and that, pursuant to section 309 (a) of the Communications Act of 1934, as amended, the said application of Conn & Cope, d/b as Denison-Texoma Broadcasting Company be, and it is hereby, designated for hearing in the above consolidated proceeding, § 1.857 of the Commission's rules and regulations not being applicable, at a time and place to be designated by subsequent order of the Commission, upon the following issues:

1. To determine the legal, technical, financial, and other qualifications of the applicant partnership and the partners to construct and operate the proposed station.

2. To determine the areas and populations which may be expected to gain primary service from the operation of the proposed station and the character of other broadcast service available to those areas and populations.

3. To determine the type and character of program service proposed to be rendered and whether it would meet the requirements of the populations and areas proposed to be served.

4. To determine whether the operation of the proposed station would involve objectionable interference with station KVSO, Ardmore, Oklahoma, or with any other existing broadcast stations and, if so, the nature and extent thereof, the areas and populations affected thereby, and the availability of other broadcast service to such areas and populations.

5. To determine whether the operation of the proposed station would involve objectionable interference with the services proposed in the pending application of Burton V. Hammond (File No. BP-5786; Docket No. 8177) or in any other pending applications for broadcast facilities and, if so, the nature and extent thereof, the areas and populations affected thereby, and the availability of other broadcast service to such areas and populations.

6. To determine whether the installation and operation of the proposed station would be in compliance with the Commission's rules and Standards of Good Engineering Practice Concerning Standard Broadcast Stations.

7. To determine on a comparative basis which, if any, of the applications in this consolidated proceeding should be granted.

It is further ordered, That the order of the Commission dated March 6, 1947 designating the applications of Terrell Broadcast Corporation and Burton V. Hammond, Jr., for hearing in a consolidated proceeding, be, and it is hereby, amended to include the application of Conn & Cope, d/b as Denison-Texoma Broadcasting Company, and to change Issue No. 7 of said order to read as Issue No. 7 stated above;

It is further ordered, That John F. Easley, licensee of station KVSO, Ardmore, Oklahoma, be, and he is hereby, made a party to this proceeding.

By the Commission.

[SEAL] T. J. SLOWIE,
Secretary.

[F. R. Doc. 47-3256; Filed, Apr. 3, 1947; 8:46 a. m.]

[Docket No. 8254]

MT. PLEASANT BROADCASTING CO.

ORDER DESIGNATING APPLICATION FOR CONSOLIDATED HEARING ON STATED ISSUES

In re application of Winston O. Ward db/as Mt. Pleasant Broadcasting Company, Mt. Pleasant, Texas, docket No. 8254, File No. BP-5439; for construction permit.

At a session of the Federal Communications Commission, held at its offices in Washington, D. C., on the 27th day of March 1947;

The Commission having under consideration the above-entitled application of Winston O. Ward db/as Mt. Pleasant Broadcasting Company, requesting a construction permit for a new standard broadcast station to operate on 1340 kc, 250 w power, unlimited time, at Mt. Pleasant, Texas;

It is ordered, That, pursuant to section 309 (a) of the Communications Act of 1934, as amended, the said application of Winston O. Ward db/as Mt. Pleasant Broadcasting Company be, and it is hereby, designated for hearing at a time and place to be designated by subsequent order of the Commission, upon the following issues:

1. To determine the legal, technical, financial, and other qualifications of the applicant to construct and operate the proposed station.

2. To determine the areas and populations which may be expected to gain or lose primary service from the operation of the proposed station and the character of other broadcast service available to those areas and populations.

3. To determine the type and character of program service proposed to be rendered and whether it would meet the

requirements of the populations and areas proposed to be served.

4. To determine whether the operation of the proposed station would involve objectionable interference with stations KAND, Corsicana, Texas, KRMD, Shreveport, Lousiana, or with any other existing broadcast stations and, if so, the nature and extent thereof, the areas and populations affected thereby, and the availability of other broadcast service to such areas and populations.

5. To determine whether the operation of the proposed station would involve objectionable interference with the services proposed in any pending applications for broadcast facilities and, if so, the nature and extent thereof, the areas and populations affected thereby, and the availability of other broadcast service to such areas and populations.

6. To determine whether the installation and operation of the proposed station would be in compliance with the Commission's rules and Standards of Good Engineering Practice Concerning Standard Broadcast Stations.

It is hereby ordered that Alto, Inc., licensee of Station KAND, Corsicana, Texas, and T. B. Lanford, R. M. Dean, Mrs. T. B. Lanford, Sr., and Mrs. R. M. Dean, a partnership, d/b as Radio Station KRMD, licensee of Station KRMD, Shreveport, Louisiana, be, and they are hereby, made parties to this proceeding.

Notice is hereby given that § 1.857 of the Commission's rules and regulations is not applicable to this proceeding.

By the Commission.

[SEAL] T. J. SLOWIE, *Secretary.*

[F. R. Doc. 47-3255; Filed, Apr. 3, 1947; 8:46 a. m.]

[Docket No. 8266]

HEIGHTS BROADCASTING CO.

ORDER DESIGNATING APPLICATION FOR CONSOLIDATED HEARING ON STATED ISSUES

In re application of The Heights Broadcasting Company, Cleveland. Ohio, Docket No. 8266, File No. BP-5412; for construction permit.

At a session of the Federal Communications Commission, held at its offices in Washington, D. C., on the 27th day of March 1947;

The Commission having under consideration the above-entitled application of The Heights Broadcasting Company for a construction permit for a new standard broadcast station to operate on the frequency 710 kc, with 250 w power, daytime only, at Cleveland, Ohio;

It is ordered, That, pursuant to section 309 (a) of the Communications Act of 1934, as amended, the said application be, and it is hereby, designated for hearing at a time and place to be designated by subsequent order of the Commission, upon the following issues:

1. To determine the legal, technical, financial, and other qualifications of the applicant corporation, its officers, directors and stockholders to construct and operate the proposed station.

2. To determine the areas and populations which may be expected to gain or lose primary service from the operation of the proposed station and the character of other broadcast service available to those areas and populations.

3. To determine the type and character of program service proposed to be rendered and whether it would meet the requirements of the populations and areas proposed to be served.

4. To determine whether the operation of the proposed station would involve objectionable interference with station WLW, Cincinnati, Ohio, or with any other existing broadcast stations and, if so, the nature and extent thereof, the areas and populations affected thereby, and the availability of other broadcast service to such areas and populations.

5. To determine whether the operation of the proposed station would involve objectionable interference with the services proposed in any pending application for broadcast facilities and, if so, the nature and extent thereof, the areas and populations affected thereby, and the availability of other broadcast service to such areas and populations.

6. To determine whether the installation and operation of the proposed station would be in compliance with the Commission's rules and Standards of Good Engineering Practice Concerning Standard Broadcast Stations.

It is further ordered, That Crosley Broadcasting Corporation, licensee of station WLW, Cincinnati, Ohio, be, and it is hereby, made a party to this proceeding.

Notice is hereby given that § 1.857 of the Commission's rules and regulations is not applicable to this proceeding.

By the Commission.

[SEAL] T. J. SLOWIE, *Secretary.*

[F. R. Doc. 47-3257; Filed, Apr. 3, 1947; 8:47 a. m.]

[Docket No. 8267]

CREST BROADCASTING CO., INC.

ORDER DESIGNATING APPLICATION FOR CONSOLIDATED HEARING ON STATED ISSUES

In re application of Crest Broadcasting Company, Incorporated, Pascagoula, Mississippi, Docket No. 8267, File No. BP-5422; for construction permit.

At a session of the Federal Communications Commission, held at its offices in Washington, D. C., on the 27th day of March 1947;

The Commission having under consideration the above-entitled application of Crest Broadcasting Company, Incorporated, for a new standard broadcast station to operate on the frequency 800 kc, with 250 w power, daytime only, at Pascagoula, Mississippi;

It is ordered, That, pursuant to section 309 (a) of the Communications Act of 1934, as amended, the said application of Crest Broadcasting Company, Incorporated, be, and it is hereby, designated for hearing at a time and place to be designated by subsequent order of the Commission, upon the following issues:

1. To determine the legal, technical, financial, and other qualifications of the applicant corporation, its officers, directors and stockholders to construct and operate the proposed station.

2. To determine the areas and populations which may be expected to gain primary service from the operation of the proposed station and the character of other broadcast service available to those areas and populations.

3. To determine the type and character of program service proposed to be rendered and whether it would meet the requirements of the populations and areas proposed to be served.

4. To determine whether the operation of the proposed station would involve objectionable interference with any existing broadcast stations and, if so, the nature and extent thereof, the areas and populations affected thereby, and the availability of other broadcast service to such areas and populations.

5. To determine whether the operation of the proposed station would involve objectionable interference with the services proposed in any pending applications for broadcast facilities and, if so, the nature and extent thereof, the areas and populations affected thereby, and the availability of other broadcast service to such areas and populations.

6. To determine whether the operation of the proposed station would deliver more than 5 uv/m ground wave signal at the nearest point on the Mexican border in violation of the provisions of the North American Regional Broadcasting Agreement.

7. To determine whether the installation and operation of the proposed station would be in compliance with the Commission's rules and Standards of Good Engineering Practice Concerning Standard Broadcast Stations.

Notice is hereby given that § 1.857 of the Commission's rules and regulations is not applicable to this proceeding.

By the Commission.

[SEAL] T. J. SLOWIE, *Secretary.*

[F. R. Doc. 47-3254; Filed, Apr. 3, 1947; 8:46 a. m.]

FLORENCE BROADCASTING CO.

PUBLIC NOTICE CONCERNING PROPOSED TRANSFER OF CONTROL [1]

The Commission hereby gives notice that on March 19, 1947, there was filed with it an application (BTC-543) for its consent under section 310 (b) of the Communications Act to the proposed transfer of control of Florence Broadcasting Company, licensee of WOLS, from M. F. Schnibben to Melvin H. Purvis. The proposal to transfer control arises out of contracts of July 15, 1941 and January 21, 1947, pursuant to which M. F. Schnibben agrees to sell to Melvin H. Purvis his 500 shares (50% interest) in the common voting $100 par value stock of said Florence Broadcast-

[1] § 1.321, Part I, Rules of practice and procedure.

ing Company for a total consideration of $40,000 payable in cash immediately after the approval of the transfer of said stock by the Federal Communications Commission. Further information as to the arrangements may be found with the application and associated papers which are on file at the offices of the Commission in Washington, D. C.

On July 25, 1946, the Commission adopted § 1.388 (known as § 1.321 effective September 11, 1946) which sets out the procedure to be followed in such cases including the requirement for public notice concerning the filing of the application. Pursuant thereto the Commission was advised by letter on March 25, 1947, that starting on March 25, 1947, notice of the filing of the application would be inserted in the Florence, South Carolina, Morning News, a newspaper of general circulation at Florence, South Carolina, in conformity with the above rule.

In accordance with the procedure set out in said rule, no action will be had upon the application for a period of 60 days from March 25, 1947, within which time other persons desiring to apply for the facilities involved may do so upon the same terms and conditions as set forth in the above described contract.

(Sec. 310 (b), 48 Stat. 1086; 47 U. S. C. A. 310 (b))

[SEAL] FEDERAL COMMUNICATIONS COMMISSION,
T. J. SLOWIE,
Secretary.

[F. R. Doc. 47-3258; Filed, Apr. 3, 1947; 8:47 a. m.]

STATION WIGM

PUBLIC NOTICE CONCERNING PROPOSED ASSIGNMENT OF LICENSE [1]

The Commission hereby gives notice that on February 13, 1947 there was filed with it an application (BAL-588) for its consent under section 310 (b) of the Communications Act to the proposed assignment of license of WIGM, Medford, Wisconsin from George F. Meyer to Dairyland's Broadcasting Service, Incorporated. The proposal to assign the license arises out of a contract of December 14, 1946 pursuant to which George F. Meyer agrees to sell to Dairyland's Broadcasting Service, Incorporated all the assets and station properties (technical and non-technical) of station WIGM for a total consideration of $30,000 payment to be made upon delivery of the bill of sale and/or delivery of the warranty deed within 30 days following date of approval of the assignment by the Federal Communications Commission. Further information as to the arrangements may be found with the application and associated papers which are on file at the offices of the Commission in Washington, D. C.

On July 25, 1946 the Commission adopted § 1.388 (known as § 1.321 effective September 11, 1946) which sets out the procedure to be followed in such cases including the requirement for public notice concerning the filing of the application. Pursuant thereto the Commission was advised by letter on March 15, 1947 that starting on March 13, 1947 notice of the filing of the application would be inserted in the Marshfield News-Herald, a newspaper of general circulation at Medford, Wisconsin in conformity with the above rule.

In accordance with the procedure set out in said rule, no action will be had upon the application for a period of 60 days from March 13, 1947 within which time other persons desiring to apply for the facilities involved may do so upon the same terms and conditions as set forth in the above described contract.

(Sec. 310 (b), 48 Stat. 1086; 47 U. S. C. A. 310 (b))

[SEAL] FEDERAL COMMUNICATIONS COMMISSION,
T. J. SLOWIE,
Secretary.

[F. R. Doc. 47-3259; Filed, Apr. 3, 1947; 8:47 a. m.]

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[1] § 1.321, Part I, Rules of practice and procedure.

FEDERAL POWER COMMISSION

[Docket No. G-500]

NORTHERN NATURAL GAS CO.

NOTICE OF APPLICATION

MARCH 31, 1947.

Notice is hereby given that on March 14, 1947, an application was filed with the Federal Power Commission by Northern Natural Gas Company (Applicant), a Delaware corporation, having its principal place of business in Omaha, Nebraska, for a certificate of public convenience and necessity pursuant to section 7 of the Natural Gas Act, as amended, to authorize Applicant to construct and operate 4,508 feet of 4½-inch O. D. branch pipe line extending from a point of connection with Applicant's 20-inch main pipe line to the Nebraska Ordnance Plant near Mead, Nebraska, and a measuring station at the end of such branch line, located in Sections 14 and 15, Township 14 North, Range 8 East, Saunders County, Nebraska, for the purpose of delivery and sale by Applicant of the entire gas requirements of the Nebraska Ordnance Plant.

A temporary certificate of public convenience and necessity authorizing the construction and operation by Applicant of the above described facilities was issued in the Commission's order of November 11, 1943, in Docket No. G-500 conditioned that, in the event Applicant desires to continue such facilities and operation beyond the period of the temporary certificate, Applicant shall then apply for a certificate of public convenience and necessity therefor in the manner prescribed by the Commission under the Natural Gas Act, as amended. The facilities above described have been in operation since the date of initial service, December 14, 1943, and are now in service.

Applicant estimates the natural gas requirements of the Nebraska Ordnance Plant for the years 1947, 1948, and 1949, will be 350 Mcf. on a maximum day and 37,000 Mcf. annually.

Applicant states that the total investment in the above described facilities as of December 31, 1946, is $8,331.

Any interested State commission is requested to notify the Federal Power Commission as to the nature of its interest in the matter and whether it desires a conference, the creation of a board, or a joint or concurrent hearing, together with the reasons for such request.

The application of Northern Natural Gas Company is on file with the Commission and is open to public inspection. Any person desiring to be heard or to make any protest with reference to the application shall file with the Federal Power Commission, Washington 25, D. C., not later than fifteen days from the date of publication of this notice in the FEDERAL REGISTER, a petition to intervene or protest. Such petition or protest shall conform to the requirements of the rules of practice and procedure (effective September 11, 1946) and shall set out clearly and concisely the facts from which the nature of the petitioner's or protestant's alleged right or interest can be determined. Petitions for intervention shall state fully and completely the grounds of the proposed intervention and the contentions of the petitioner in the proceeding, so as to advise the parties and the Commission as to the issues of fact or law to be raised or controverted, by admitting, denying, or explaining, specifically and in detail, each material allegation of fact or law asserted with respect to the application.

[SEAL] LEON M. FUQUAY,
Secretary.

[F. R. Doc. 47-3217; Filed, Apr. 3, 1947; 8:45 a. m.]

[Project 1966]

WISCONSIN PUBLIC SERVICE CORP.

NOTICE OF APPLICATION FOR LICENSE

APRIL 1, 1947.

Public notice is hereby given pursuant to the provisions of the Federal Power Act (16 U. S. C. 791-825r), that Wisconsin Public Service Corporation, of Milwaukee, Wisconsin, has made application for license for constructed major Project No. 1966, known as the Grandfather Falls project, located on Wisconsin River in Lincoln County, Wisconsin, and consisting of a concrete and stone masonry dam; a reservoir; two powerhouses, the upper powerhouse built integral with the dam and having installed hydraulic capacity of 2,660 horsepower and the lower powerhouse located about one mile downstream having installed hydraulic capacity of 23,050 horsepower; a canal about 4,000 feet long; two penstocks about 1,315 feet long; two substations; and appurtenant works. Any protests

against approval of this application or request for hearing thereon, with the reasons for such protest or request, and the name and address of the party or parties so protesting or requesting, should be submitted before April 30, 1947 to the Federal Power Commission at Washington, D. C.

[SEAL] LEON M. FUQUAY, *Secretary.*

[F. R. Doc. 47-3224; Filed, Apr. 3, 1947; 8:45 a. m.]

SECURITIES AND EXCHANGE COMMISSION

[File No. 70-1262]

MICHIGAN GAS AND ELECTRIC CO., THE MIDDLE WEST CORP.

ORDER GRANTING EXTENSION OF TIME

At a regular session of the Securities and Exchange Commission, held at its office in the City of Philadelphia, Pa., on the 28th day of March 1947.

The Commission, by order dated July 29, 1946, having granted and permitted to become effective an application-declaration, as amended, filed pursuant to the Public Utility Holding Company Act of 1935 jointly by The Middle West Corporation, a registered holding company, and its subsidiary, Michigan Gas and Electric Company, and Halsey, Stuart & Co., Inc., an affiliate of Michigan Gas and Electric Company, which application-declaration proposed a recapitalization of Michigan Gas and Electric Company and related transactions; and

The Commission, upon request of the applicants-declarants, having, by orders dated October 21 and November 29, 1946, and February 3, 1947, extended to March 31, 1947 the time within which such transactions may be carried out as provided in Rule U-24; and

Applicants-declarants now having requested a further extension of time, for a period of approximately thirty days from March 31, 1947, within which such transactions may be carried out and having stated that Michigan Gas and Electric Company has now filed an amendment to its Registration Statement, heretofore filed under the Securities Act of 1933, and that such extension is necessary to permit consummation of the proposed transactions after such amended Registration Statement becomes effective; and

The Commission having considered such request and deeming it appropriate in the public interest and in the interest of investors and consumers that such request be granted:

It is ordered, That the time within which the transactions heretofore approved by order of July 29, 1946, may be carried out under Rule U-24 be, and hereby is, extended to and including April 30, 1947.

By the Commission.

[SEAL] ORVAL L. DUBOIS, *Secretary.*

[F. R. Doc. 47-3218; Filed, Apr. 3, 1947; 8:45 a. m.]

[File No. 70-1459]

UNION ELECTRIC CO. OF MO.

NOTICE OF FILING OF DECLARATION

At a regular session of the Securities and Exchange Commission held at its office in the City of Philadelphia, Pa., on the 28th day of March 1947.

Notice is hereby given that Union Electric Company of Missouri (Missouri Union), a registered holding company and a subsidiary of The North American Company, has filed with the Commission a declaration pursuant to the Public Utility Holding Company Act of 1935 ("act"). Declarant designates section 12 (b) of the act and Rule U-45 promulgated under the act as applicable to the proposed transaction.

Notice is further given that any interested person may, not later than April 7, 1947, at 5:30 p. m., e. s. t., request the Commission in writing that a hearing be held on such matter, stating the nature of his interest, the reasons for such request and the issues, if any, of fact or law raised by said declaration proposed to be controverted, or may request that he be notified if the Commission should order a hearing thereon. At any time thereafter such declaration, as filed or as amended, may become effective as provided in Rule U-23 of the rules and regulations promulgated pursuant to said act, or the Commission may exempt such transaction as provided in Rule U-20 (a) and U-100 thereof. Any such request should be addressed: Secretary, Securities and Exchange Commission, 18th and Locust Streets, Philadelphia 3, Pennsylvania.

All interested persons are referred to said declaration which is on file in the office of this Commission, for a statement of the transactions therein proposed, which are summarized below:

Missouri Union proposes to advance on open account, with interest at 2% per annum, up to the sum of $250,000 to its indirect non-utility subsidiary Union-Colliery Company (Colliery) for the purpose of enabling its subsidiary to meet payments due on equipment for operation of its new coal mine. Declarant states that the proposed transaction supplements the program of Colliery set forth in its amended declaration permitted to become effective by order of the Commission dated December 29, 1945 (Holding Company Act Release No. 6350) regarding the proposed issuance by Colliery of $1,000,000 aggregate principal amount of Bank Loan Notes bearing interest at 2% per annum, maturing in installments from December 31, 1947, to December 31, 1951.

By the Commission.

[SEAL] ORVAL L. DUBOIS, *Secretary.*

[F. R. Doc. 47-3221; Filed, Apr. 3, 1947; 8:45 a. m.]

[File No. 70-1496]

ELECTRIC POWER & LIGHT CORP. AND MISSISSIPPI POWER & LIGHT CO.

NOTICE REGARDING FILING OF APPLICATION-DECLARATION

At a regular session of the Securities and Exchange Commission, held at its office in the City of Philadelphia, Pennsylvania, on the 28th day of March A. D. 1947.

Notice is hereby given that a joint application-declaration has been filed with this Commission pursuant to the Public Utility Holding Company Act of 1935 by Electric Power & Light Corporation ("Electric"), a registered holding company, and its subsidiary, Mississippi Power & Light Company ("Mississippi"). Applicants-declarants have designated sections 6 (a), 7, 9 (a), 10 and 12 (f) of the act and Rule U-43 promulgated thereunder as applicable to the proposed transactions.

Notice is further given that any interested person may, not later than April 7, 1947 at 5:30 p. m., e. s. t., request the Commission in writing that a hearing be held on such matter, stating the nature of his interest, the reason for such request and the issues, if any, of fact or law raised by said application-declaration which he desires to controvert, or may request that he be notified if the Commission should order a hearing thereon. Any such request should be addressed: Secretary, Securities and Exchange Commission, 18th and Locust Streets, Philadelphia 3, Pennsylvania. At any time after April 7, 1947, said application-declaration, as filed or as amended, may be granted and permitted to become effective as provided in Rule U-23 of the rules and regulations promulgated under the act, or the Commission may exempt such transactions as provided in Rule U-20 (a) and Rule U-100 thereof.

All interested persons are referred to said application-declaration which is on file in the offices of this Commission for a statement of the transactions therein proposed which are summarized below:

Electric is the owner of all of the outstanding common stock of Mississippi consisting of 700,000 shares without par value having a stated value of $7,000,000. Mississippi proposes to issue and sell, and Electric proposes to acquire, an additional 250,000 shares of common stock of Mississippi for a cash consideration of $2,500,000. The proceeds from the sale of the new common stock will be used by Mississippi for the construction of needed facilities. Electric proposes to use treasury funds in making the proposed purchase.

Applicants-declarants request that the Commission's order be issued as soon as possible and become effective upon the issuance thereof in order to permit consummation of the proposed transactions at the earliest possible opportunity.

By the Commission.

[SEAL] ORVAL L. DUBOIS, *Secretary.*

[F. R. Doc. 47-3220; Filed, Apr. 3, 1947; 8:45 a. m.]